

Exhibit B

Marc R. Toggia, M.D.

Page 1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., :MASTER FILE NO.
PELVIC REPAIR SYSTEM PRODUCTS :2:12-MD-02327
LIABILITY LITIGATION :MDL 2327

THIS DOCUMENT RELATES TO THE :
FOLLOWING CASES IN WAVE 1 OF :
THE MDL 200: :
Betty Funderburke :JOSEPH R. GOODWIN
Case No. 2:12-cv-00957 :U.S. DISTRICT JUDGE
:
Patricia Conti :
Case No. 2:12-cv-00516 :
:
Donna Massey :
Case No. 2:12-cv-00880 :
:
Amanda Deleon :
Case No. 2:12-cv-00358 :
:
Wilma Johnson :
Case No. 2:12-cv-00809 :
:
Harriet Beach :
Case No. 2:12-cv-00476 :
:
Virginia Dixon :
Case No. 2:12-cv-01081 :
:

March 24, 2016

DEPOSITION OF MARC R. TOGLIA, M.D.

GOLKOW TECHNOLOGIES, INC.
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Marc R. Toglia, M.D.

Page 2	Page 4
<p>1</p> <p>2 --- March 24, 2016 ---</p> <p>3</p> <p>4</p> <p>5 Oral sworn deposition of MARC R. TOGLIA, 6 M.D., held at RADNOR HOTEL, 591 East Lancaster 7 Avenue, Wayne, Pennsylvania, commencing at 1:20 8 p.m., before Margaret M. Reihl, a Registered 9 Professional Reporter, Certified Realtime 10 Reporter, and Notary Public.</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 I N D E X</p> <p>2 WITNESS: Page MARC R. TOGLIA, M.D.</p> <p>3</p> <p>4 By Mr. Schnieders 7 5 By Mr. Snell 254</p> <p>6 E X H I B I T S</p> <p>7</p> <p>8 TOGLIA DEPOSITION EXHIBITS MARKED</p> <p>9 No. 1 Notice to Take Deposition 8 of Marc Toglia, M.D.</p> <p>10 No. 2 Curriculum Vitae of 36 Marc Richard Toglia, M.D.</p> <p>11</p> <p>12 No. 3 Website printout of 65 Urogynecology Associates of Philadelphia</p> <p>13</p> <p>14 No. 4 Box of materials relied on 75</p> <p>15 No. 5 Invoices of Marc R. Toglia, (two pages) 77</p> <p>16 No. 6 Expert Report of Marc R. Toglia, M.D. 77</p> <p>17</p> <p>18 No. 7 Marc Toglia Reliance List in Addition to Materials Referenced in Report 79</p> <p>19</p> <p>20 No. 8 E-mail string, top one dated 7/21/09 [ETH.MESH.00585587 through 585589] 90</p> <p>21</p> <p>22 No. 9 E-mail string, top one dated 1/26/10 [ETH.MESH.01221280 through 01221283] 101</p> <p>23</p> <p>24</p>
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<p>1 A P P E A R A N C E S:</p> <p>2</p> <p>3 WAGSTAFF & CARTMELL, LLP 4 BY: CHRISTOPHER L. SCHNIEDERS, ESQUIRE 5 4740 Grand Avenue 6 Suite 300 7 Kansas City, Missouri 64112 8 (816) 701-1145 9 cschnieders@wcllp.com 10 Counsel for Plaintiffs</p> <p>11</p> <p>12 BUTLER SNOW LLP 13 BY: NILS B. (BURT) SNELL, ESQUIRE 14 500 Office Center Drive 15 Suite 400 16 Fort Washington, Pennsylvania 19034 17 (267) 513-1884 18 burt.snell@butlersnow.com 19 Counsel for Defendant</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 No. 10 Gynecare, Gynemesh PS pamphlet Released: 03 Feb 2015 137</p> <p>2</p> <p>3 No. 11 Gynecare, Gynemesh PS pamphlet copyright 2008 [ETH.MESH.02342218 through 02342249] 141</p> <p>4</p> <p>5 No. 12 Slide deck, "KOL Strategy" dated February 2008 [ETH.MESH.01177099] 163</p> <p>6</p> <p>7 No. 13 E-mail string, top one dated 11/30/10 [ETH.MESH.05131435 through 05131436] 177</p> <p>8 No. 14 Chart, Accurate HCP Report 180</p> <p>9 No. 15 Chart, HCP Cognos report run 11.17.10 with all end dates in 2010 & some 2011 [ETH.MESH.17782434] 183</p> <p>10</p> <p>11 No. 16 Ethicon Master Consulting Agreement [ETH.MESH.05277161 through 05277171] 185</p> <p>12</p> <p>13 No. 17 E-mail dated 2/16/12, with attached Master Consulting Agreement for Marc Toglia, M.D. [ETH.MESH.09158028] 189</p> <p>14</p> <p>15</p> <p>16 No. 18 Consulting Agreement Requisition Form-Part I, for Marc Toglia [ETH.MESH.07635991 through 07636003] 190</p> <p>17</p> <p>18 No. 19 E-mail string, top one dated 11/19/10 [ETH.MESH.07386591 through 07386592] 194</p> <p>19</p> <p>20 No. 20 E-mail string, top one dated 2/9/09 [ETH.MESH.07383824 through 07383825] 197</p> <p>21</p> <p>22 No. 21 E-mail string, top one dated 10/3/10 [ETH.MESH.15186000 through 15186001] 203</p> <p>23</p> <p>24</p>

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<p>1 No. 22 E-mail dated 4/21/11 [ETH.MESH.10818812 through 10818813] 206</p> <p>2</p> <p>3 No. 23 E-mail string, top one dated 4/7/10 [ETH.MESH.09211317 through 09211318] 209</p> <p>4</p> <p>5 No. 24 E-mail string, top one dated 5/6/10 [ETH.MESH.09217182 through 09217183] 213</p> <p>6</p> <p>7 No. 25 TVT Exact: Editor's Backgrounder [ETH.MESH.09210943 through 09210947] 217</p> <p>8 No. 26 E-mails dated 4/5/10 [ETH.MESH.09211216] 221</p> <p>9</p> <p>10 No. 27 Roadmap charts [ETH.MESH.02229625 through 02229633] 223</p> <p>11 No. 28 Document titled "Overview" [ETH.MESH.03898389 through 03898398] 225</p> <p>12</p> <p>13 No. 29 Slide deck, "The Mesh Story" [ETH.MESH.16440031] 234</p> <p>14 No. 30 ProPublica, Dollars for Docs 248</p> <p>15 ---</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 the notice that has asked you to come here today and</p> <p>2 hand it to you.</p> <p>3 A. Sure.</p> <p>4 (Document marked for identification as</p> <p>5 Toglia Deposition Exhibit No. 1.)</p> <p>6 BY MR. SCHNIEDERS:</p> <p>7 Q. Have you seen this document before,</p> <p>8 Doctor?</p> <p>9 A. I have.</p> <p>10 Q. And we were talking about this briefly</p> <p>11 beforehand, but you've brought some documents with you</p> <p>12 here today; is that correct?</p> <p>13 A. Yes, I have.</p> <p>14 Q. Okay. I'm going to go through Schedule</p> <p>15 A, and you just tell me what you brought today that is</p> <p>16 responsive to those things, and I'm going to ask you</p> <p>17 some questions on if there are other things that you</p> <p>18 haven't brought today that are responsive as well,</p> <p>19 okay?</p> <p>20 A. Yes.</p> <p>21 Q. Number 1, this is on Page 7, a complete</p> <p>22 copy of your Curriculum Vitae?</p> <p>23 A. I believe that's part of my expert</p> <p>24 report.</p>
Page 7	Page 9
<p>1 ... MARC R. TOGLIA, M.D., having been duly</p> <p>2 sworn as a witness, was examined and testified</p> <p>3 as follows ...</p> <p>4 BY MR. SCHNIEDERS:</p> <p>5 Q. Good afternoon, Doctor.</p> <p>6 A. Good afternoon.</p> <p>7 Q. My name is Chris Schnieders, and I'm</p> <p>8 here on behalf of the plaintiff steering committee to</p> <p>9 take your deposition based upon an expert report that</p> <p>10 you wrote for a couple of products.</p> <p>11 Do you understand that today?</p> <p>12 A. Yes.</p> <p>13 Q. Would you please state your name for the</p> <p>14 record.</p> <p>15 A. Mark Richard Toglia.</p> <p>16 Q. And I believe, Dr. Toglia, that you have</p> <p>17 given a deposition related to your TVT report already;</p> <p>18 is that correct?</p> <p>19 A. That is correct.</p> <p>20 Q. And you understand that we are here</p> <p>21 today on the Gynemesh PS and Prolift report that you</p> <p>22 had written?</p> <p>23 A. Yes, I do.</p> <p>24 Q. Doctor, I'm going to mark as Exhibit 1</p>	<p>1 Q. Number 2, "Any and all documents in your</p> <p>2 possession, including but not limited to,</p> <p>3 correspondence, notes, videos, CDs, DVDs, flash or USB</p> <p>4 drives, photographs, databases or materials in other</p> <p>5 form provided to you or created by you which relate to</p> <p>6 your opinions, expected testimony or development of</p> <p>7 your opinions in this litigation."</p> <p>8 A. Yes.</p> <p>9 Q. Have you brought everything that you</p> <p>10 believe that you have is responsive in regard to Number</p> <p>11 2?</p> <p>12 A. Yes.</p> <p>13 Q. Number 3, "Any and all documents</p> <p>14 reviewed by you in preparation for this deposition."</p> <p>15 A. Yes, I have.</p> <p>16 Q. Okay. And, Doctor, I believe off the</p> <p>17 record we had discussed the fact that all you've</p> <p>18 brought with you today are literature that is in your</p> <p>19 reliance list and your expert reports; is that correct?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. So you have not reviewed any</p> <p>22 documents in preparation for your deposition here today</p> <p>23 that were not in your reliance list?</p> <p>24 A. I mean, with the understanding that this</p>

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Marc R. Toggia, M.D.

<p style="text-align: right;">Page 10</p> <p>1 is what I do for a living, there's a tremendous amount 2 of stuff that I do read and review, in general, that's 3 on the subject matter, but I believe that the stuff 4 that's in my report is on the reliance list. 5 MR. SNELL: Just for clarification, 6 counsel, are you asking about things he's 7 reviewed since his report or depositions of 8 plaintiffs' experts, things like that, because, 9 obviously, those were not available to him at 10 the pertinent time. 11 MR. SCHNIEDERS: I'm asking for anything 12 at this point with Number 3 that he has 13 reviewed in preparation for this deposition 14 here today. 15 BY MR. SCHNIEDERS: 16 Q. Does that cover it, Doctor? 17 A. Essentially, yes. Understand that I 18 also have access to information that is not published 19 and that I am not at liberty to share because I'm an 20 editor for journals and I review for -- so, obviously, 21 I have not brought that, but I don't quote or cite that 22 information in my report. 23 Q. Are you relying on any unpublished 24 information --</p>	<p style="text-align: right;">Page 12</p> <p>1 A. Yes, that's correct. 2 Q. So is it fair to say that whatever 3 information this is you're talking about, you didn't 4 review it in anticipation for this deposition? 5 A. Right. 6 Q. Did you review any depositions that are 7 not on your reliance list? 8 A. Again, I've got the Ostergard 9 deposition, which I only recently received, so I don't 10 know if that would be on the list or not, but I did 11 bring the deposition with me. 12 MR. SNELL: Since we're the ones who 13 generated the list, it would not be on there, 14 since the list was -- I took Ostergard's 15 deposition, it was a week or two at least after 16 he produced expert reports, so I do not think 17 it's on there. I haven't even looked. 18 MR. SCHNIEDERS: Well, and I believe, 19 counsel, did we receive a new reliance list 20 yesterday. 21 MR. SNELL: It wasn't a new reliance 22 list. It was, essentially, a corrected one. I 23 think the paralegals attached his sling TVT 24 reliance list to both his TVT report and his</p>
<p style="text-align: right;">Page 11</p> <p>1 A. I'm sorry. I'm not relying upon -- 2 sure, I'm not relying upon that information. 3 Q. Okay. Did you review that information 4 in preparation for your deposition here today? 5 A. That is information that I have reviewed 6 for my own role outside of this deposition, so not in 7 preparation for this deposition. 8 Q. Has your counsel been privy to those 9 documents? 10 A. He has not. 11 MR. SNELL: I'm not his counsel. 12 MR. SCHNIEDERS: I'm sorry. 13 THE WITNESS: I'm sorry. Does that 14 make -- is my intent clear with that? 15 BY MR. SCHNIEDERS: 16 Q. Well, if we're going to be clear, I 17 think what you're telling me is that you may have come 18 about information outside of this litigation that has 19 not informed your opinions in this litigation in any 20 way, shape or form, correct? 21 A. Correct. 22 Q. And you're not relying upon that 23 information to put forth your opinions in this case, 24 correct?</p>	<p style="text-align: right;">Page 13</p> <p>1 prolapse report, instead of attaching the right 2 prolapse list to the prolapse report. So it's 3 not amended or updated or anything like that. 4 It's just they stuck the wrong one on the POP 5 report. 6 MR. SCHNIEDERS: Okay. So the list that 7 was produced yesterday was the list as of the 8 date of the issuance of the report? 9 MR. SNELL: Like 29th to 30th of 10 February. 11 MR. SCHNIEDERS: And did you bring a 12 copy of that list that was produced yesterday 13 because I don't know if I have that list to 14 mark as an exhibit here today. 15 MR. SNELL: Do you have a copy? 16 THE WITNESS: This, POP? 17 MR. SNELL: If you want to take that, 18 you can mark it. 19 MR. SCHNIEDERS: We'll get to that in a 20 second. 21 MR. SNELL: But as to your question, I 22 doubt Ostergard's deposition was on this, I 23 don't see it on here. 24 BY MR. SCHNIEDERS:</p>

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<p>1 Q. Doctor, have you reviewed any documents</p> <p>2 since your deposition on the TVT report that you hadn't</p> <p>3 previously reviewed before the TVT report deposition?</p> <p>4 MR. SNELL: Form.</p> <p>5 THE WITNESS: Yes, the information as it</p> <p>6 relates to Gynemesh and Prolift were not part</p> <p>7 of my TVT report.</p> <p>8 BY MR. SCHNIEDERS:</p> <p>9 Q. But you issued those reports at the same</p> <p>10 time, didn't you?</p> <p>11 A. No. This report was issued February 26,</p> <p>12 2016. The other report was issued back in October.</p> <p>13 Q. Okay. Doctor, have you brought --</p> <p>14 strike that.</p> <p>15 You haven't brought -- are there any</p> <p>16 photographs or other images including photographs of</p> <p>17 the plaintiffs, the plaintiffs' explanted mesh or</p> <p>18 products taken by you or for you which relate to your</p> <p>19 opinions in this case?</p> <p>20 A. No.</p> <p>21 Q. Have you brought any Ethicon products in</p> <p>22 your possession?</p> <p>23 A. I don't have any Ethicon -- oh, Ethicon</p> <p>24 products, no.</p>	<p>1 A. No.</p> <p>2 Q. How have you communicated with defense</p> <p>3 counsel in this case?</p> <p>4 A. By phone.</p> <p>5 Q. Have you ever e-mailed with defense</p> <p>6 counsel?</p> <p>7 A. Not an opinion or the stuff that you</p> <p>8 just referred to, no.</p> <p>9 Q. So nothing about compensation rates or</p> <p>10 bill sheets or anything like that?</p> <p>11 A. No.</p> <p>12 Q. Did you collect a retainer in this case?</p> <p>13 A. I did not.</p> <p>14 Q. Do you typically collect retainers in</p> <p>15 cases in which you --</p> <p>16 A. I do not.</p> <p>17 Q. And if you let me finish my questions,</p> <p>18 I'll let you start off after that, if you don't mind,</p> <p>19 because otherwise we'll get on top of each other.</p> <p>20 So, as I sit here, I've got two invoices that</p> <p>21 are dated January 31st of 2016 and February 29th of</p> <p>22 2016, and that is all of the time that you have billed</p> <p>23 to date in the Ethicon Gynecare mesh litigation titled</p> <p>24 MDL 200? I'm just reading off of this.</p>
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<p>1 Q. "Any and all documents, including time</p> <p>2 sheets, invoices, time records, billing records which</p> <p>3 record or document the work performed, time spent or</p> <p>4 charges made in connection with your expert opinion in</p> <p>5 this matter."</p> <p>6 A. I have my invoices, yes.</p> <p>7 Q. And are they here today?</p> <p>8 A. I'm sorry. What is the date of the last</p> <p>9 invoice? There should be a date end of February.</p> <p>10 Q. Yeah, there's a February 29th of this</p> <p>11 year.</p> <p>12 A. Right.</p> <p>13 Q. Is that the most recent invoice?</p> <p>14 A. Most recent invoice that I have</p> <p>15 submitted, correct.</p> <p>16 Q. Any communication between you and your</p> <p>17 counsel -- I'm sorry, strike that.</p> <p>18 Any communication between you and counsel for</p> <p>19 the defendants, to the extent such communications</p> <p>20 relate to your compensation; identify facts or data</p> <p>21 that you were provided and that you considered in</p> <p>22 forming your opinions; or identify assumptions that</p> <p>23 plaintiffs' counsel provided you and that you relied on</p> <p>24 in forming your opinions.</p>	<p>1 A. That is everything I have billed to</p> <p>2 date.</p> <p>3 Q. When were you first contacted to work in</p> <p>4 this case?</p> <p>5 A. End of August 2015.</p> <p>6 Q. All right. Moving through the notice to</p> <p>7 get through that, Number 10, any and all documents,</p> <p>8 including consulting agreements, time sheets, invoices,</p> <p>9 time records, billing records which record or document</p> <p>10 the work performed, time spent or charges made in</p> <p>11 connection with consulting related to studies,</p> <p>12 consulting work, cadaver labs, professional education</p> <p>13 training and any other work that has been compensated</p> <p>14 by defendants or expert fees charged to defendant</p> <p>15 related to any female pelvic mesh product sold by</p> <p>16 Ethicon for treatment of stress urinary incontinence or</p> <p>17 pelvic organ prolapse.</p> <p>18 Did you bring any documents related to</p> <p>19 Number 10?</p> <p>20 MR. SNELL: I'll just note for the</p> <p>21 record, I think we filed objections as to some</p> <p>22 of these requests. Go ahead.</p> <p>23 THE WITNESS: I don't believe we've</p> <p>24 provided any of that.</p>

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<p style="text-align: right;">Page 18</p> <p>1 BY MR. SCHNIEDERS:</p> <p>2 Q. Have you provided any of that to defense</p> <p>3 counsel?</p> <p>4 A. I don't have an independent recollection</p> <p>5 that I have.</p> <p>6 Q. Whether you have provided it to defense</p> <p>7 counsel or not, do you have documents that would fall</p> <p>8 under category 10?</p> <p>9 A. I don't have documents. If I'm not</p> <p>10 mistaken, at the TVT deposition we did cover the amount</p> <p>11 and extent of my participation and compensation from</p> <p>12 Ethicon.</p> <p>13 Q. I appreciate that, Doctor, but as far as</p> <p>14 the documents that have been requested here at Number</p> <p>15 10, do you have any responsive documents in your</p> <p>16 possession?</p> <p>17 A. Like I said, they were covered in the</p> <p>18 TVT deposition, that's all. That's all I have.</p> <p>19 Q. You produced all the documents you had</p> <p>20 in your possession as part of the TVT deposition?</p> <p>21 A. I don't recall the specifics, but I do</p> <p>22 recall that we went over all that on record, correct?</p> <p>23 MR. SNELL: Yeah, I think he did produce</p> <p>24 whatever he had.</p>	<p style="text-align: right;">Page 20</p> <p>1 tax, it might be five years, I can't remember,</p> <p>2 three to five years I discard them.</p> <p>3 BY MR. SCHNIEDERS:</p> <p>4 Q. Just so we're clear on the record, right</p> <p>5 now we're talking about things that are outside of</p> <p>6 litigation, correct?</p> <p>7 A. Understood.</p> <p>8 Q. And so when is the last time that you</p> <p>9 consulted outside of litigation with Ethicon?</p> <p>10 MR. SNELL: Object. This is covered in</p> <p>11 his first deposition, but go ahead.</p> <p>12 THE WITNESS: It's to the best of my</p> <p>13 recollection, and it is a guesstimate at best,</p> <p>14 2011. It's not been -- not in my working</p> <p>15 memory.</p> <p>16 BY MR. SCHNIEDERS:</p> <p>17 Q. Do you recall in the last six months</p> <p>18 destroying any of these kind of documents?</p> <p>19 A. No, I did not.</p> <p>20 Q. So is it your testimony here today that</p> <p>21 you have no documents that are responsive to Number 10</p> <p>22 in your possession that you have not previously</p> <p>23 produced as part of your TVT deposition?</p> <p>24 A. Yes, it is.</p>
<p style="text-align: right;">Page 19</p> <p>1 THE WITNESS: Right.</p> <p>2 MR. SNELL: I think this is the same as</p> <p>3 what he produced -- whatever he had, he</p> <p>4 produced.</p> <p>5 THE WITNESS: Right, yes.</p> <p>6 BY MR. SCHNIEDERS:</p> <p>7 Q. So you produced consulting agreements?</p> <p>8 A. I don't know the answer to that. I</p> <p>9 don't recall.</p> <p>10 Q. Do you have consulting agreements with</p> <p>11 Ethicon?</p> <p>12 A. None actively, no.</p> <p>13 Q. Do you have the paper that reflects the</p> <p>14 consulting agreement with Ethicon?</p> <p>15 A. No, I do not.</p> <p>16 Q. You don't keep any of those for your</p> <p>17 files?</p> <p>18 A. No.</p> <p>19 Q. Do you keep records of your invoices</p> <p>20 that you send to Ethicon?</p> <p>21 MR. SNELL: Object to form. Go ahead.</p> <p>22 THE WITNESS: I don't have the records,</p> <p>23 no. I haven't done consulting with Ethicon in</p> <p>24 years, and I discard such things after usual</p>	<p style="text-align: right;">Page 21</p> <p>1 Q. Is that because the documents are all in</p> <p>2 the possession of your practice?</p> <p>3 A. I don't believe they are.</p> <p>4 Q. Okay. Well, if we go back, Doctor, and</p> <p>5 see from the TVT deposition that there wasn't anything</p> <p>6 produced that's responsive to Number 10 from you, are</p> <p>7 there responsive documents somewhere that you have?</p> <p>8 A. I think I've answered that. I do not</p> <p>9 have what you're asking for in my possession, because I</p> <p>10 have not had any active consulting agreement with</p> <p>11 Ethicon for more than five years. I certainly have not</p> <p>12 destroyed anything since I was contacted by Mr. Snell</p> <p>13 regarding these matters.</p> <p>14 Q. And you were contacted in August of</p> <p>15 2015?</p> <p>16 A. I believe so.</p> <p>17 THE WITNESS: Does that sound right to</p> <p>18 you?</p> <p>19 MR. SNELL: I can't testify, but I think</p> <p>20 you're in the right ballpark.</p> <p>21 THE WITNESS: Okay.</p> <p>22 MR. SNELL: And this is to the best of</p> <p>23 your recollection.</p> <p>24 THE WITNESS: To the best of my</p>

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<p>1 recollection.</p> <p>2 BY MR. SCHNIEDERS:</p> <p>3 Q. How were you contacted by Mr. Snell?</p> <p>4 A. Telephone.</p> <p>5 Q. Did you know Mr. Snell prior to that</p> <p>6 conversation?</p> <p>7 A. No, I did not.</p> <p>8 Q. Did you know any of Mr. Snell's partners</p> <p>9 prior to that?</p> <p>10 A. No, I do not.</p> <p>11 Q. Had you ever worked on a legal case</p> <p>12 prior to Mr. Snell contacting you?</p> <p>13 MR. SNELL: Form.</p> <p>14 THE WITNESS: I had worked on</p> <p>15 malpractice cases but not product liability</p> <p>16 cases.</p> <p>17 BY MR. SCHNIEDERS:</p> <p>18 Q. So you served as an expert witness in a</p> <p>19 medical malpractice case before?</p> <p>20 A. I have.</p> <p>21 Q. We'll talk about that in just one</p> <p>22 moment.</p> <p>23 MR. SNELL: Counsel, this was all</p> <p>24 covered in depth in the TVT deposition.</p>	<p>1 have the transcript. There weren't any.</p> <p>2 MR. SNELL: I don't have the transcript</p> <p>3 with me.</p> <p>4 MR. SCHNIEDERS: Okay. Let's not waste</p> <p>5 time on it, all right.</p> <p>6 BY MR. SCHNIEDERS:</p> <p>7 Q. Number 11, "Copies of Schedule C and</p> <p>8 Form 1099 of your tax records for the preceding five</p> <p>9 (5) tax years, as well as any other documentation that</p> <p>10 reflects consulting and/or expert fees charged to</p> <p>11 defendants (with personal information and any other</p> <p>12 information unrelated to consulting fees redacted)."</p> <p>13 MR. SNELL: We objected to that, and</p> <p>14 this witness will not be producing his tax</p> <p>15 forms.</p> <p>16 MR. SCHNIEDERS: And what's the basis of</p> <p>17 that objection?</p> <p>18 MR. SNELL: Invades his privacy, all the</p> <p>19 bases we set forth. Your experts have not</p> <p>20 produced any of their tax forms.</p> <p>21 BY MR. SCHNIEDERS:</p> <p>22 Q. Number 12, "All correspondence,</p> <p>23 memoranda, e-mails and/or any other documentation</p> <p>24 reflecting communications (including written,</p>
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<p>1 MR. SCHNIEDERS: Taking my deposition,</p> <p>2 Burt, you can talk about whatever you want.</p> <p>3 They're responsive questions.</p> <p>4 MR. SNELL: Actually, no, you're not,</p> <p>5 because the parties have an agreement; there</p> <p>6 shall not be duplicative discovery of experts.</p> <p>7 MR. SCHNIEDERS: I've looked through the</p> <p>8 entire transcript, and I'm very comfortable</p> <p>9 that I'm asking the right questions, not to</p> <p>10 mention the fact that you've given me a whole</p> <p>11 other reliance list that I got yesterday, so</p> <p>12 I've got to ask my questions and see what's out</p> <p>13 there. There weren't any consulting agreements</p> <p>14 produced as part of the TVT deposition.</p> <p>15 MR. SNELL: I know that because he</p> <p>16 didn't have any, but I think he told you they</p> <p>17 were marked. They were definitely discussed in</p> <p>18 that deposition. I don't have the deposition</p> <p>19 with me, but I know for a fact that they were</p> <p>20 marked.</p> <p>21 MR. SCHNIEDERS: Well, I just read it</p> <p>22 again last night so -- and those consulting</p> <p>23 agreements would have been there and, okay, you</p> <p>24 can look at what's been marked in there, if you</p>	<p>1 electronic and/or oral) with any employees of</p> <p>2 defendants related to any female pelvic mesh product</p> <p>3 sold by Ethicon, Inc. for treatment of stress urinary</p> <p>4 incontinence or pelvic organ prolapse."</p> <p>5 Have you produced any such correspondence,</p> <p>6 memoranda, e-mails or other documentation, Doctor?</p> <p>7 A. I believe I answered earlier that I</p> <p>8 don't have any of those correspondence in my</p> <p>9 possession.</p> <p>10 Q. What's your current e-mail address?</p> <p>11 A. I think that's personal information.</p> <p>12 That's not a question I'm willing to answer on the</p> <p>13 record.</p> <p>14 Q. Is it @ATT.net address?</p> <p>15 A. I'm not going to answer that question.</p> <p>16 Q. Is that on counsel's instruction or on</p> <p>17 your own volition?</p> <p>18 A. I don't see how that's relevant to my</p> <p>19 role. I'm here to discuss my expert report and my</p> <p>20 opinions in that regard.</p> <p>21 Q. In your communication with sales</p> <p>22 representatives for the defendant, did you ever use</p> <p>23 your personal e-mail address?</p> <p>24 MR. SNELL: I'm going to object. This</p>

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<p>1 is irrelevant. This is, I think, covered in</p> <p>2 the first deposition, and you're about to get</p> <p>3 into areas that -- well, we'll leave it at</p> <p>4 that.</p> <p>5 MR. SCHNIEDERS: I think I know what</p> <p>6 you're talking about, and I don't intend to go</p> <p>7 anywhere near that, so you can relax on that.</p> <p>8 THE WITNESS: I'm not trying to be</p> <p>9 obstructive or difficult, but to the best of my</p> <p>10 knowledge, I don't recall ever using personal</p> <p>11 e-mail to respond -- well, I don't, I don't. I</p> <p>12 don't remember. I don't recall.</p> <p>13 BY MR. SCHNIEDERS:</p> <p>14 Q. I'll be fair to you on this, Doctor.</p> <p>15 I'm not trying to elicit some of what I think you're</p> <p>16 thinking I'm trying to elicit right now.</p> <p>17 A. I understand.</p> <p>18 Q. In your first deposition there were some</p> <p>19 e-mails where you did, and I'm not talking about any</p> <p>20 specific instance, but there were e-mails back and</p> <p>21 forth with other people that are involved in Ethicon in</p> <p>22 their professional capacity?</p> <p>23 A. Correct, right, okay, correct. But I</p> <p>24 don't have in my possession any of that, those</p>	<p>1 Q. Any others?</p> <p>2 A. No, no.</p> <p>3 Q. And the Sphinx never made it to market,</p> <p>4 correct?</p> <p>5 A. It never made it past the conceptual</p> <p>6 stage. Does that make sense to you?</p> <p>7 Q. It does.</p> <p>8 A. Okay.</p> <p>9 Q. Number 13 is duplicative of some of the</p> <p>10 other ones. I'm assuming you are going to tell me that</p> <p>11 you have produced everything that is responsive to</p> <p>12 Number 13; is that correct, Doctor?</p> <p>13 A. That would be my position, correct.</p> <p>14 Q. Number 14, "All documents related to</p> <p>15 deponent's involvement with Ethicon's professional</p> <p>16 education, including, but not limited to any and all</p> <p>17 PowerPoints, course materials, outlines, videos or</p> <p>18 presentations, live surgical presentations, marketing</p> <p>19 evaluations created by or provided to deponent related</p> <p>20 to any female pelvic mesh product sold by Ethicon, Inc.</p> <p>21 for treatment of stress urinary incontinence or pelvic</p> <p>22 organ prolapse.</p> <p>23 Do you have any responsive documents to Number</p> <p>24 14?</p>
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<p>1 transcripts, I don't have any copies or -- I don't have</p> <p>2 copies of those e-mails. I haven't used an AT&T</p> <p>3 address in I don't know how long.</p> <p>4 Q. And did -- with your new address which</p> <p>5 I've also seen on some e-mails, did you go back when</p> <p>6 you received this notice to review to see if you had</p> <p>7 any responsive e-mails?</p> <p>8 A. I did not have any responsive e-mails.</p> <p>9 Q. You looked for them?</p> <p>10 A. Yes. The last -- I mean, the last</p> <p>11 communications I had with Ethicon had nothing to do</p> <p>12 with any of the stuff that we're discussing today.</p> <p>13 They were on projects that were unrelated to any of</p> <p>14 this.</p> <p>15 Q. What projects?</p> <p>16 A. They were projects for other products</p> <p>17 that are not related to Gynemesh or Prolift.</p> <p>18 Q. Okay. They were other products that</p> <p>19 were made or in production or premarket by Ethicon?</p> <p>20 A. They were concepts for potential</p> <p>21 products within this sphere of female pelvic floor</p> <p>22 disorders.</p> <p>23 Q. Like the Sphinx?</p> <p>24 A. Correct.</p>	<p>1 A. I do not have any of those items in my</p> <p>2 possession.</p> <p>3 Q. You didn't keep any PowerPoints or</p> <p>4 anything you put together?</p> <p>5 A. No. To be clear, I never created any of</p> <p>6 those talks. There were talks that might have been</p> <p>7 provided to me. Once my consulting arrangement changed</p> <p>8 and I threw things out, I don't really keep that stuff.</p> <p>9 Q. They were provided to you by Ethicon,</p> <p>10 right?</p> <p>11 A. Products related, right. I mean, I</p> <p>12 think some of them we have -- we have brought, the</p> <p>13 Prolift professional education materials. Nothing</p> <p>14 different than that.</p> <p>15 MR. SNELL: Right, but I think he's</p> <p>16 asking you did you have -- do you have any from</p> <p>17 back when you were a consultant, not stuff that</p> <p>18 you reviewed and prepared that's on the thumb</p> <p>19 drives.</p> <p>20 MR. SCHNIEDERS: Right.</p> <p>21 MR. SNELL: I think that's what he's</p> <p>22 asking about.</p> <p>23 MR. SCHNIEDERS: That's correct.</p> <p>24 THE WITNESS: No, I don't have it.</p>

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<p style="text-align: right;">Page 30</p> <p>1 BY MR. SCHNIEDERS:</p> <p>2 Q. Just so we're clear on the record here,</p> <p>3 Doctor, you've given talks on behalf of Ethicon, right?</p> <p>4 A. Correct.</p> <p>5 Q. You've used presentations in those talks</p> <p>6 at times like PowerPoints, right?</p> <p>7 A. That were provided to me by Ethicon.</p> <p>8 Q. And those were put together by Ethicon</p> <p>9 for you to present?</p> <p>10 A. Correct.</p> <p>11 Q. And you don't have any of those in your</p> <p>12 possession, as we sit here today, correct?</p> <p>13 A. I do not.</p> <p>14 Q. Okay. Number 15, "Any and all materials</p> <p>15 including, but not limited to, protocols, results,</p> <p>16 adverse events, minutes for study meeting related to</p> <p>17 any clinical trials and/or studies of any type related</p> <p>18 to deponent's work as consultant for defendant in any</p> <p>19 capacity related to any female pelvic mesh product sold</p> <p>20 by Ethicon, Inc. for treatment of stress urinary</p> <p>21 incontinence or pelvic organ prolapse."</p> <p>22 Do you have any responsive documents, Doctor?</p> <p>23 A. I do not.</p> <p>24 Q. Are you currently involved in enrolling</p>	<p style="text-align: right;">Page 32</p> <p>1 A. I do not.</p> <p>2 Q. Have you ever reported an adverse event</p> <p>3 to the FDA?</p> <p>4 A. I have.</p> <p>5 Q. Do you ever keep a record of that?</p> <p>6 A. No.</p> <p>7 Q. Have you ever reported an adverse event</p> <p>8 related an Ethicon product to the FDA?</p> <p>9 A. I have.</p> <p>10 Q. On how many occasions?</p> <p>11 A. I don't know the answer to that.</p> <p>12 Q. Ballpark, ten?</p> <p>13 A. Ten may be a reasonable guess.</p> <p>14 Q. Have you ever reported any adverse</p> <p>15 events to the FDA for any of the products we're here to</p> <p>16 talk about today?</p> <p>17 A. I have.</p> <p>18 Q. Can you tell me which products?</p> <p>19 A. Prolift, I'd say three or five.</p> <p>20 Q. Any for Gynemesh PS?</p> <p>21 A. No.</p> <p>22 Q. Any for TVT?</p> <p>23 A. Not that I can specifically recall.</p> <p>24 Hold on.</p>
<p style="text-align: right;">Page 31</p> <p>1 in a clinical trial?</p> <p>2 A. I am not.</p> <p>3 Q. So just so we're clear, anything that is</p> <p>4 responsive to Number 15 you've either produced or don't</p> <p>5 have anymore, correct?</p> <p>6 A. Correct.</p> <p>7 Q. "16. Any reports/documents, whether</p> <p>8 kept in hard copy or electronic form, relating to any</p> <p>9 other matter involving any female pelvic mesh product</p> <p>10 for treatment of stress urinary incontinence or pelvic</p> <p>11 organ prolapse."</p> <p>12 Do you have any responsive documents to Number</p> <p>13 16, Doctor?</p> <p>14 A. I do not.</p> <p>15 Q. You don't keep anything on any other</p> <p>16 female pelvic products?</p> <p>17 A. I do not.</p> <p>18 Q. "Any and all documents, including</p> <p>19 transcripts or statements, between you and any</p> <p>20 governmental agency regarding any female pelvic mesh</p> <p>21 product used for treatment of stress urinary</p> <p>22 incontinence or pelvic organ prolapse."</p> <p>23 Do you have any responsive documents to Number</p> <p>24 17, Doctor?</p>	<p style="text-align: right;">Page 33</p> <p>1 In all honesty, most of the reports that I have</p> <p>2 filed with the MAUDE probably involved non-Ethicon</p> <p>3 products.</p> <p>4 Q. Any particular reason?</p> <p>5 A. I think that they reflect what -- these</p> <p>6 were not products that I personally had implanted, but</p> <p>7 they were women that I subsequently cared for, and it</p> <p>8 just simply reflects the nature of my referral</p> <p>9 practice.</p> <p>10 Q. Because as a physician, you have a duty</p> <p>11 when you find out about an adverse event to report it,</p> <p>12 regardless of how you come about that information,</p> <p>13 right?</p> <p>14 MR. SNELL: Objection, calls for a legal</p> <p>15 conclusion.</p> <p>16 BY MR. SCHNIEDERS:</p> <p>17 Q. Was that a yes, Doctor?</p> <p>18 A. I have reported events that I have come</p> <p>19 across as a surgeon.</p> <p>20 Q. And my point is just that regardless of</p> <p>21 whether or not it's your patient or you find out about</p> <p>22 it from another manner, you would still report an</p> <p>23 adverse event because you have a duty as a doctor to do</p> <p>24 that, correct?</p>

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<p>1 MR. SNELL: Objection, calls for legal 2 conclusion. 3 THE WITNESS: I'm not so sure about the 4 duty, but my personal practice is to report 5 those events. 6 BY MR. SCHNIEDERS: 7 Q. And it's fair to say that with regard to 8 types of mesh products that we're talking about here 9 today, and I'm talking about the entire spectrum, 10 regardless of Ethicon or other manufacturers, that 11 you've reported more adverse events for the other 12 manufacturers than Ethicon? 13 MR. SNELL: Form. 14 THE WITNESS: I would say that is likely 15 true. 16 BY MR. SCHNIEDERS: 17 Q. Do you have any recollection of what 18 product you've likely reported the most times as an 19 adverse event? 20 A. I do. 21 Q. Which product is that? 22 A. I believe Apogee Perigee. 23 Q. Do you have any idea of how many adverse 24 events you reported on that product?</p>	<p>1 (Document marked for identification as 2 Toggia Deposition Exhibit No. 2.) 3 MR. SCHNIEDERS: I'm going to hand you 4 your CV, which I've marked as Exhibit 2. 5 BY MR. SCHNIEDERS: 6 Q. Doctor, this looks like this was revised 7 at the top right there on 8/13 of 2015; is that 8 correct? 9 A. Yes. 10 Q. Is this your most current CV? 11 A. Yes. 12 Q. Doctor, you are what's called a 13 urogynecologist, correct? 14 A. Actually, I am a specialist in female 15 pelvic medicine and reconstructive surgery, which was 16 formerly referred to as urogynecology. 17 Q. I see in 2013 that you went to get a 18 board certification in female pelvic medicine and 19 reconstructive surgery. 20 Can you tell me what that entailed? 21 A. I didn't go in 2013. I went in 2012 and 22 in 2013 I received certification. So female pelvic 23 medicine and reconstructive surgery is the fourth 24 subspecialty within the specialty of obstetrics and</p>
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<p>1 A. I do not. 2 Q. Number 18 says, "Any and all documents 3 relating to an presentations, PowerPoints or lectures 4 regarding any female pelvic mesh product used for 5 treatment of stress urinary incontinence and pelvic 6 organ prolapse." 7 Is your answer the same as it was regarding the 8 materials themselves that you don't have anything in 9 your possession? 10 A. That is correct. 11 Q. Lastly, Number 19, "Any demonstrative 12 exhibits, such as graphics or charts, prepared by or on 13 your behalf for use at trial." 14 Do you have any responsive documents? 15 A. We're talking about other than what has 16 already been provided either in my TVT deposition or 17 currently? 18 Q. Yes. 19 A. I have nothing in addition. 20 Q. You can set that to the side. 21 MR. SCHNIEDERS: I'm going to do a 22 little housekeeping here because I actually 23 premarked a few things, and I'm going to get 24 off track if I don't do it the right way.</p>	<p>1 gynecology. It is duly accredited by both the American 2 Board of Obstetrics and Gynecology and the American 3 Urologic Board. 4 This involved -- this is a multipart process 5 culminating in taking and passing a written exam. 6 Prior to that, there were demonstration of adequate 7 case volume and level of training. For example, you 8 had to be previously board certified either by the 9 American Board of OB-GYN in OB-GYN or the American -- 10 the ABU, the American Board of Urology. 11 Q. And was that a facility locally that you 12 were able to go and do some of this work, or how did 13 that actually work out? 14 A. Well, the process is guided by the 15 ACGME, the American College of Graduate Medical 16 Education. The exam itself was taken via computer by 17 local sites throughout the country, locally through 18 some of the different learning centers. 19 Q. Prior to 2013 when you received the 20 board certification and began your work, did you 21 consider yourself to be a specialist in the area of 22 female pelvic medicine and reconstructive surgery? 23 A. That's correct. 24 Q. How many people nationwide hold this</p>

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<p style="text-align: right;">Page 38</p> <p>1 subspecialty, if you know?</p> <p>2 A. So in 2013 approximately 750 of us were</p> <p>3 board certified, and 2014/2015 there might have been</p> <p>4 the addition of another 100 or so each year. I</p> <p>5 couldn't give you the final number. I'm sure it's</p> <p>6 something that's readily available, but I'm going to</p> <p>7 guesstimate we're talking about 1,200 individuals who</p> <p>8 are currently board certified in the subspecialty.</p> <p>9 Many others, including some of your experts,</p> <p>10 did not sit for the boards, but this is still their</p> <p>11 area of expertise and practice.</p> <p>12 Q. Did any pharmaceutical company or device</p> <p>13 company in any way, shape or form fund or help with</p> <p>14 your board certification?</p> <p>15 A. No, none whatsoever.</p> <p>16 Q. They didn't sponsor any programs that</p> <p>17 had to do with it?</p> <p>18 A. No.</p> <p>19 Q. Do you have any academic appointments,</p> <p>20 Doctor?</p> <p>21 A. I do. They're listed on my CV.</p> <p>22 Q. And when I say that, are you employed by</p> <p>23 any of these facilities?</p> <p>24 A. I am not.</p>	<p style="text-align: right;">Page 40</p> <p>1 Q. Okay.</p> <p>2 A. And it's actually the chair of coding.</p> <p>3 Q. Okay. And in your position as vice</p> <p>4 chair and now chair, what are your duties?</p> <p>5 A. I represent the society nationally at</p> <p>6 meetings such as the CPT, the RUC. I interact directly</p> <p>7 with the government through CMS. I represent the</p> <p>8 society as a liaison member to the American College of</p> <p>9 Obstetrics and Gynecology, and I either head or direct</p> <p>10 certain task forces as they relate to coding and health</p> <p>11 economics within the sphere of female pelvic medicine.</p> <p>12 Q. Okay. And if I say AUGS, you know what</p> <p>13 I'm talking about, right?</p> <p>14 A. I do.</p> <p>15 Q. So your position as vice chair, then</p> <p>16 chair of this committee with AUGS is tied to this</p> <p>17 bottom one here, where it says "Member, ACOG Committee</p> <p>18 of Health Economics and Coding, AUGS Liaison"?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. Tell me what AUGS is.</p> <p>21 A. AUGS is a professional organization of</p> <p>22 healthcare providers, which includes physicians,</p> <p>23 physical therapists, nurse specialists that are</p> <p>24 interested in promoting excellence in female pelvic</p>
<p style="text-align: right;">Page 39</p> <p>1 Q. Do you teach any classes?</p> <p>2 A. I teach clinically, I give lectures. I</p> <p>3 don't teach classes in the sense that a college</p> <p>4 professor would teach classes.</p> <p>5 Q. On Page 2 and, obviously, you know your</p> <p>6 CV so you probably don't need it to talk through it,</p> <p>7 but I see that you're a member currently of some</p> <p>8 professional societies. I think I know which ones they</p> <p>9 are, but there was a couple typos later on, so I just</p> <p>10 want to make clear which of these professional</p> <p>11 societies are you currently a member of?</p> <p>12 A. Sure. I'm currently a member of the</p> <p>13 American Urogynecologic Society, the Society for</p> <p>14 Gynecologic Surgeons, the International Urogynecology</p> <p>15 Society, which is not on this list, I don't think. I'm</p> <p>16 a fellow of the American College of Obstetrics and</p> <p>17 Gynecology as well.</p> <p>18 Q. Okay. And moving to the next page, it</p> <p>19 appears that you hold or at least held as of 2015 a</p> <p>20 vice chair position for the Committee for Government</p> <p>21 Relations and Coding at the American Urogynecologic</p> <p>22 Society; is that correct?</p> <p>23 A. I'm currently the chair of that</p> <p>24 committee.</p>	<p style="text-align: right;">Page 41</p> <p>1 medicine and reconstructive surgery.</p> <p>2 Q. Is it sponsored by any pharmaceutical or</p> <p>3 device companies?</p> <p>4 A. It is not.</p> <p>5 Q. What about ACOG, tell me what ACOG is.</p> <p>6 A. ACOG is the professional organization,</p> <p>7 it's the American College and Congress of Obstetrics</p> <p>8 and Gynecology that is based out of Washington, DC and</p> <p>9 comprises the professional members, again, doctors,</p> <p>10 nurse practitioners, other healthcare providers in the</p> <p>11 specialty of obstetrics and gynecology.</p> <p>12 Q. Okay. And is ACOG sponsored or funded</p> <p>13 by any pharmaceutical or device companies?</p> <p>14 A. No.</p> <p>15 Q. And you're sure about that with regard</p> <p>16 to AUGS and ACOG?</p> <p>17 A. I am certain about that.</p> <p>18 Q. Down here under Hospital Service it</p> <p>19 says, "System Chief, Division of Female Pelvic Medicine</p> <p>20 and Reconstructive Pelvic Surgery, Main Line Health."</p> <p>21 What is Main Line Health?</p> <p>22 A. Main Line Health is the largest health</p> <p>23 system here in Philadelphia. It's a not-for-profit</p> <p>24 system consisting of four hospitals.</p>

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<p style="text-align: right;">Page 42</p> <p>1 Q. And do you have privileges at all four 2 of those hospitals?</p> <p>3 A. I have privileges at all four hospitals.</p> <p>4 Q. Is there any particular hospital you do 5 the majority of your procedures at?</p> <p>6 A. Yes.</p> <p>7 Q. Which one is that?</p> <p>8 A. I split my time clinically between Paoli 9 Hospital located in Paoli, Pennsylvania and Riddle 10 Hospital located in Media, Pennsylvania.</p> <p>11 Q. If you want to move on, Doctor, to Page 12 4, there is a section at the bottom there that's called 13 "Past Clinical Research Projects."</p> <p>14 Do you see that?</p> <p>15 A. I do.</p> <p>16 Q. And it looks to me as if there are nine 17 times in your past in which you've participated in a 18 clinical study; is that correct?</p> <p>19 MR. SNELL: Hold on. Did you say nine?</p> <p>20 MR. SCHNIEDERS: That's what I see, 21 because I'm skipping ten, so I'm going to ask 22 him separately.</p> <p>23 MR. SNELL: I'm going to object to form.</p> <p>24 BY MR. SCHNIEDERS:</p>	<p style="text-align: right;">Page 44</p> <p>1 next time, but I realize this comes up, but I don't 2 have my own set of private things that I can correct 3 these things on, but I will tell you that that is an 4 old trial that has already been published.</p> <p>5 Q. And that's my question, Number 10 then, 6 is that the actual trial that you did go on to publish?</p> <p>7 A. Yes.</p> <p>8 Q. That's listed as Number 23 under your 9 publications?</p> <p>10 A. Yes.</p> <p>11 Q. Doctor, other than 23, are there any 12 publications that you have ever made with regard to any 13 mesh product?</p> <p>14 MR. SNELL: Form.</p> <p>15 THE WITNESS: Twenty-four is an 16 editorial that I wrote that talked about 17 sacrocolpopexy, which would involve the mesh, 18 but that is an editorial.</p> <p>19 BY MR. SCHNIEDERS:</p> <p>20 Q. But no other articles other than those 21 two?</p> <p>22 A. Article 16 was a study I published with 23 my own patient population. Some of those patients did 24 have a mesh procedure, although, to the best of my</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. You tell me, because ten seems to be a 2 bit different, because I asked you earlier if you were 3 in the process of enrolling patients, and you told me 4 no. So let's just start with 1 through 9. It looks 5 like there were several clinical research projects you 6 were involved with?</p> <p>7 MR. SNELL: I'll just note for the 8 record this issue in Number 10 and the 9 statement about currently enrolling patients I 10 know was covered in his prior deposition.</p> <p>11 MR. SCHNIEDERS: I'll let you make your 12 objections. If I can finish my questions 13 before you start them, if you don't mind.</p> <p>14 MR. SNELL: Go ahead. Covered.</p> <p>15 BY MR. SCHNIEDERS:</p> <p>16 Q. So, Doctor --</p> <p>17 A. I've participated in ten, and I am not 18 currently enrolling.</p> <p>19 Q. Okay. And tell me why that is?</p> <p>20 A. Because this is simply a typographical 21 error, and that was covered in my deposition with the 22 TVT trial. And my apologies, the problem is I can't 23 make corrections because these belong to the Court. If 24 I had another copy, I'm happy to correct that for the</p>	<p style="text-align: right;">Page 45</p> <p>1 knowledge, we did not stipulate what that was.</p> <p>2 Q. But fair to say that that article was 3 primarily about polyester sutures?</p> <p>4 MR. SNELL: Form.</p> <p>5 THE WITNESS: As the title suggests, it 6 was about both long-term surgical outcomes as 7 well as wound complications in that population.</p> <p>8 BY MR. SCHNIEDERS:</p> <p>9 Q. All right, Doctor, I'd like to switch 10 topics now, and I'd like to start with your first work 11 with Ethicon.</p> <p>12 It's my understanding that you were recruited 13 by Dr. Lucente; is that correct?</p> <p>14 MR. SNELL: Objection, asked, and this 15 is all covered in his first deposition.</p> <p>16 THE WITNESS: No, I was not recruited by 17 Dr. Lucente.</p> <p>18 BY MR. SCHNIEDERS:</p> <p>19 Q. Well, how would you characterize it?</p> <p>20 MR. SNELL: Objection, asked and 21 answered, prior covered.</p> <p>22 THE WITNESS: How I was contacted by 23 Ethicon?</p> <p>24 BY MR. SCHNIEDERS:</p>

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<p style="text-align: right;">Page 46</p> <p>1 Q. Yes.</p> <p>2 A. I don't recall the specifics. I would</p> <p>3 have been contacted probably by a product manager.</p> <p>4 Q. Approximately what year would that have</p> <p>5 been?</p> <p>6 MR. SNELL: Same objection. This is all</p> <p>7 covered in the prior deposition.</p> <p>8 THE WITNESS: 1999.</p> <p>9 BY MR. SCHNIEDERS:</p> <p>10 Q. Okay. Had you ever worked for Ethicon</p> <p>11 prior to being contacted for that consulting?</p> <p>12 A. That was the first contact.</p> <p>13 Q. Okay. Prior to 1999 had you worked with</p> <p>14 other pharmaceutical or device companies?</p> <p>15 A. I think I had, yes.</p> <p>16 Q. Which companies had you worked with</p> <p>17 prior to working with Ethicon?</p> <p>18 A. Well, I did clinical trials for what we</p> <p>19 then called Yamanouchi, which is now called Astellas.</p> <p>20 I did a clinical trial with Eli Lilly, a clinical trial</p> <p>21 with Pfizer.</p> <p>22 Q. Pharmacia?</p> <p>23 A. I did some work with Johnson & Johnson,</p> <p>24 which owns Ethicon, but at the time it was not with</p>	<p style="text-align: right;">Page 48</p> <p>1 work with Ethicon?</p> <p>2 MR. SNELL: Objection, form and covered</p> <p>3 in prior dep.</p> <p>4 THE WITNESS: I think I previously</p> <p>5 stated that initially I may have participated</p> <p>6 in some kind of market research that actually</p> <p>7 probably was prior to '99, let's say '98. I</p> <p>8 don't necessarily consider that a consulting</p> <p>9 relationship. I was just asked to give</p> <p>10 feedback from a marketing perspective on the</p> <p>11 TVT product. At some point in time, I started</p> <p>12 to get involved more in the professional</p> <p>13 education teaching, the TVT technique.</p> <p>14 Does that answer your question?</p> <p>15 BY MR. SCHNIEDERS:</p> <p>16 Q. Sure, that's the beginning. So as a</p> <p>17 preceptor, correct?</p> <p>18 A. Correct. And I also started to serve in</p> <p>19 an advisory or a consultant role.</p> <p>20 Q. What products did you serve as a</p> <p>21 preceptor for with Ethicon?</p> <p>22 A. I would say the TVT family of products,</p> <p>23 TVT, TVT obturator, TVT Secur, TVT Abbrevio, TVT Exact.</p> <p>24 Q. Did you ever serve as a preceptor for</p>
<p style="text-align: right;">Page 47</p> <p>1 Ethicon, I don't believe, no. Realize this is not</p> <p>2 directly relevant, but whether or not Monistat as a</p> <p>3 product was Ethicon versus Johnson & Johnson, I don't</p> <p>4 know.</p> <p>5 Q. But that was the product at that time?</p> <p>6 A. Correct.</p> <p>7 Q. Aside from what's listed in your past</p> <p>8 clinical research projects and the companies that</p> <p>9 you've listed as the sponsors, do you recall any other</p> <p>10 pharmaceutical companies you worked with prior to 1999?</p> <p>11 A. Yes, there were a host of them.</p> <p>12 Q. Which ones can you name for me?</p> <p>13 A. Now you're really taxing my long-term</p> <p>14 memory. Rhone-Poulenc Rorer. As you probably are</p> <p>15 aware, counselor, many of these companies have been</p> <p>16 absorbed and renamed.</p> <p>17 Q. That is Aventis now, that would be</p> <p>18 Aventis?</p> <p>19 A. Right, correct. Pharmacia Upjohn,</p> <p>20 that's probably it.</p> <p>21 Q. Other than the ones that are listed in</p> <p>22 your CV, that would be about it?</p> <p>23 A. Correct.</p> <p>24 Q. Okay. Starting in 1999, what was your</p>	<p style="text-align: right;">Page 49</p> <p>1 Gynemesh PS?</p> <p>2 A. To the best of my knowledge, no.</p> <p>3 Q. Same question with regard to Prolift?</p> <p>4 A. Yes.</p> <p>5 Q. Have you ever served as a preceptor for</p> <p>6 any company that was not Ethicon?</p> <p>7 A. I don't believe so.</p> <p>8 Q. So your relationship with Ethicon would</p> <p>9 have began with a market research consulting or</p> <p>10 whatever you want to call that in 1998 and, based upon</p> <p>11 your recollection, continued till about 2011?</p> <p>12 MR. SNELL: Object to form, previously</p> <p>13 covered.</p> <p>14 THE WITNESS: I believe so, yes.</p> <p>15 MR. SCHNIEDERS: I'm going to switch</p> <p>16 topics. Does anyone want to take a break, or</p> <p>17 are we okay?</p> <p>18 MR. SNELL: Take a five-minute break.</p> <p>19 (Brief recess taken at 2:09 p.m.)</p> <p>20 (Deposition resumes at 2:14 p.m.)</p> <p>21 BY MR. SCHNIEDERS:</p> <p>22 Q. Doctor, we're back after a short break.</p> <p>23 In your current practice, Doctor, what</p> <p>24 surgeries do you perform for stress urinary</p>

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<p style="text-align: right;">Page 50</p> <p>1 incontinence?</p> <p>2 A. Currently, we perform a combination of</p> <p>3 midurethral slings, such as TVT Exact, TVT Abbrevio. We</p> <p>4 perform periurethral bulking procedures, autologous</p> <p>5 fascial slings, retropubic urethropexies.</p> <p>6 Q. And are there any slings that you use</p> <p>7 aside from TVT products?</p> <p>8 A. There are not.</p> <p>9 Q. Have you ever used any sling aside from</p> <p>10 a TVT product?</p> <p>11 MR. SNELL: Objection.</p> <p>12 BY MR. SCHNIEDERS:</p> <p>13 Q. Strike that. Have you ever used any</p> <p>14 sling aside from an Ethicon product?</p> <p>15 MR. SNELL: Form, previously covered.</p> <p>16 THE WITNESS: Yes.</p> <p>17 BY MR. SCHNIEDERS:</p> <p>18 Q. What products have you used in addition?</p> <p>19 A. Boston Scientific, Advantage Fit, AMS</p> <p>20 RetroArc. Cook had a biologic sling, Surgisis ST,</p> <p>21 don't quote me on the trade name on that one. I think</p> <p>22 that's it.</p> <p>23 Q. Fair to say the vast majority of the</p> <p>24 slings that you've put in have been TVTs?</p>	<p style="text-align: right;">Page 52</p> <p>1 c-o-l-p-o-c-l-e-i-s-i-s.</p> <p>2 Q. What nonsurgical remedies do you use?</p> <p>3 A. Again, we will use physical therapy,</p> <p>4 pelvic floor muscle rehabilitation, pessaries.</p> <p>5 Q. Do you currently use the Gynemesh PS?</p> <p>6 A. I do.</p> <p>7 Q. How often would you say you currently</p> <p>8 use the Gynemesh PS?</p> <p>9 A. Two days a week.</p> <p>10 Q. And is that two surgeries a week, or is</p> <p>11 that on two days you use it several times?</p> <p>12 A. Two days a week I typically do between</p> <p>13 six and eight surgical procedures a week for</p> <p>14 incontinence or prolapse.</p> <p>15 Q. Okay. And specific to Gynemesh PS, how</p> <p>16 often are you using that?</p> <p>17 A. I use it two days a week, as I</p> <p>18 mentioned, perhaps maybe half my surgical repairs,</p> <p>19 maybe 40%.</p> <p>20 Q. 40% of surgical repairs of POP?</p> <p>21 A. For prolapse. It varies obviously.</p> <p>22 Q. How many pelvic organ prolapse surgeries</p> <p>23 would you estimate you have performed as a surgeon?</p> <p>24 A. Thousands. I've been in practice for</p>
<p style="text-align: right;">Page 51</p> <p>1 A. I would say 99%.</p> <p>2 Q. What nonsurgical remedies are you using</p> <p>3 for women suffering from stress urinary incontinence</p> <p>4 currently?</p> <p>5 A. Currently, we use biofeedback,</p> <p>6 electrical stimulation, pelvic floor muscle therapy.</p> <p>7 We actually have a physical therapist within the</p> <p>8 practice for that. Previously, as you can see from my</p> <p>9 CV, we were involved in the Duloxetine trial.</p> <p>10 Occasionally, we will use barrier type devices.</p> <p>11 Q. When a woman comes into your office with</p> <p>12 stress urinary incontinence, what's your first line</p> <p>13 treatment?</p> <p>14 A. Well, first line treatment starts with</p> <p>15 education, pelvic floor muscle exercises, behavioral</p> <p>16 modification, fluid management.</p> <p>17 Q. What current surgeries do you use for</p> <p>18 pelvic organ prolapse?</p> <p>19 A. Again, this is what I do for a living.</p> <p>20 There's a wide breadth of procedures that we do either</p> <p>21 abdominal, vaginal, with or without hysterectomy,</p> <p>22 native tissue plications, graft augmentation,</p> <p>23 specifically abdominal sacrocolpopexies, obliterative</p> <p>24 procedures such as colpopcleisis,</p>	<p style="text-align: right;">Page 53</p> <p>1 nearly 25 years. I have an annual surgical load that</p> <p>2 varies probably between 150 and 200 surgical procedures</p> <p>3 a year.</p> <p>4 Q. And how many times do you believe or</p> <p>5 would you estimate that you used Gynemesh PS for the</p> <p>6 surgery?</p> <p>7 A. I believe that's in my surgical --</p> <p>8 excuse me. I believe that's in my report. Off the top</p> <p>9 of my -- I just want to verify it. Off the top of my</p> <p>10 head, I believe it was 3,000, approximately 3,000</p> <p>11 within our practices.</p> <p>12 Q. And that's specific to Gynemesh PS?</p> <p>13 A. I believe so. I mean, it's Gynemesh and</p> <p>14 related materials.</p> <p>15 Q. Well, I'm going to ask, so how many</p> <p>16 Prolifts?</p> <p>17 A. Prolifts probably number 200 or more.</p> <p>18 Q. You say "and related materials," are you</p> <p>19 including the Prolift within that 3,000 for Gynemesh?</p> <p>20 A. I'm sorry, let me try to be more clear.</p> <p>21 I'm talking about specifically macroporous</p> <p>22 polypropylene graft material, which would include</p> <p>23 Gynemesh PS, Prolift predominantly.</p> <p>24 Q. Can you explain how that mesh differs</p>

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<p style="text-align: right;">Page 54</p> <p>1 from the TVT mesh?</p> <p>2 MR. SNELL: Form.</p> <p>3 THE WITNESS: Yes, I mean, they're both</p> <p>4 type 1 polypropylene mesh. I believe I covered</p> <p>5 this in my report. There are differences in</p> <p>6 terms of both weight and pore size.</p> <p>7 BY MR. SCHNIEDERS:</p> <p>8 Q. And what are the differences in weight</p> <p>9 and pore size?</p> <p>10 A. Again, I believe I've covered that in my</p> <p>11 reports. Approximately, Gynemesh PS is going to be</p> <p>12 about 42, 43 grams per meter squared. It's got a pore</p> <p>13 size of about 2,400 microns.</p> <p>14 The mesh used for TVT is approximately twice</p> <p>15 that. I believe the mesh is probably in the</p> <p>16 neighborhood of 90 grams per meter squared. The pore</p> <p>17 size is probably around 1,200 microns.</p> <p>18 Q. You said 2,400 microns for Gynemesh?</p> <p>19 A. 2.4 millimeters is the pore size.</p> <p>20 Q. Doctor, do you keep track of any</p> <p>21 complications you have with your mesh surgeries?</p> <p>22 A. Yes.</p> <p>23 MR. SNELL: Form, asked and answered</p> <p>24 earlier.</p>	<p style="text-align: right;">Page 56</p> <p>1 be me. It would be me, my partners.</p> <p>2 Q. How many partners do you have?</p> <p>3 A. I currently have one physician partner</p> <p>4 and one nurse practitioner partner.</p> <p>5 Q. And does your nurse -- or I'm sorry,</p> <p>6 your physician partner, does she review those along</p> <p>7 with you?</p> <p>8 A. My current partner who has been with me</p> <p>9 less than two years has not. My previous partner had.</p> <p>10 Q. And when you review the data that you</p> <p>11 have in your office regarding how many you've put in,</p> <p>12 what kind of report, if anything, do you output as a</p> <p>13 result of that?</p> <p>14 A. It depends. I'll offer as an example,</p> <p>15 you know, my partner at the time Dr. Fagan and I</p> <p>16 published the article that we spoke of earlier, in</p> <p>17 which we, from the database, reviewed nearly 100 women</p> <p>18 that had undergone prolapse surgery using a specific</p> <p>19 technique sacrospinous ligament suspension, and we</p> <p>20 looked at outcomes, we looked at complications,</p> <p>21 recurrences, re-operations. So temporally we may stop</p> <p>22 and look at what we've been doing to better understand</p> <p>23 what the limitations and successes are of those</p> <p>24 procedures.</p>
<p style="text-align: right;">Page 55</p> <p>1 BY MR. SCHNIEDERS:</p> <p>2 Q. How do you keep track of that?</p> <p>3 MR. SNELL: Same objection.</p> <p>4 THE WITNESS: Are you allowing me to</p> <p>5 answer?</p> <p>6 MR. SNELL: You can go ahead and answer.</p> <p>7 I mean, it's all in the report.</p> <p>8 THE WITNESS: It's changed throughout</p> <p>9 the years. Currently, our patients are</p> <p>10 enrolled in a national registry prospectively,</p> <p>11 where we keep track of all prolapse surgery.</p> <p>12 Previously, we would use private</p> <p>13 databases. Obviously, we have medical records</p> <p>14 in our office. We have electronic health</p> <p>15 records in our system. I've been in the same</p> <p>16 practice now for 19 years.</p> <p>17 BY MR. SCHNIEDERS:</p> <p>18 Q. Okay. And you keep track of all those</p> <p>19 numbers?</p> <p>20 A. The records are all available to us. We</p> <p>21 review them periodically as we go on.</p> <p>22 Q. When you say "periodically," who are</p> <p>23 "we"?</p> <p>24 A. I guess you're looking at we. We would</p>	<p style="text-align: right;">Page 57</p> <p>1 Q. Okay. And do you reduce what you look</p> <p>2 at to any sort of a tangible form that you can share</p> <p>3 with the company or other physicians?</p> <p>4 MR. SNELL: Object to form.</p> <p>5 THE WITNESS: I wouldn't share anything</p> <p>6 with a company. It has nothing to do with a</p> <p>7 company. It varies. Sometimes we review it</p> <p>8 internally and we do nothing with it.</p> <p>9 Sometimes we publish it, sometimes we present</p> <p>10 it. Sometimes this is done as part of a larger</p> <p>11 consortium of researches, such as the TVT</p> <p>12 Secur. Obviously, the prospective registry</p> <p>13 database is something that we contribute to. I</p> <p>14 guess in that regard my current partner and I</p> <p>15 contribute to that database together. Someone</p> <p>16 else is analyzing that, so it just varies.</p> <p>17 BY MR. SCHNIEDERS:</p> <p>18 Q. Do you keep track of complications as a</p> <p>19 result of your database?</p> <p>20 A. Yes.</p> <p>21 Q. And do you review those periodically as</p> <p>22 well?</p> <p>23 A. Yes.</p> <p>24 Q. When is the last time you looked at</p>

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<p style="text-align: right;">Page 58</p> <p>1 that?</p> <p>2 A. Yesterday.</p> <p>3 Q. Forgive me, Doctor, but when you look at</p> <p>4 this, what are you looking for? Are you just looking</p> <p>5 at straight numbers? What is it that you're seeing?</p> <p>6 A. It depends upon the clinical question</p> <p>7 that at the time we're interested in looking at. It's,</p> <p>8 you know, currently we've been looking at voiding</p> <p>9 function following midurethral slings in our patients,</p> <p>10 how they are at, say, one month. You know, we'll look</p> <p>11 at our rates of retention, need for revision, things</p> <p>12 like that.</p> <p>13 Q. Do you have a number of women that</p> <p>14 needed revisions that you implanted mesh in?</p> <p>15 MR. SNELL: Form.</p> <p>16 THE WITNESS: It's a very, very small</p> <p>17 number.</p> <p>18 BY MR. SCHNIEDERS:</p> <p>19 Q. Well, let me ask you this, Doctor: Can</p> <p>20 you tell me how many revisions you've performed in your</p> <p>21 career?</p> <p>22 MR. SNELL: Object. I think this was</p> <p>23 covered in prior depo.</p> <p>24 THE WITNESS: It was.</p>	<p style="text-align: right;">Page 60</p> <p>1 MR. SCHNIEDERS: I'm asking him a</p> <p>2 question. If he says I'm not stating it right,</p> <p>3 then please do, Doctor. I'll ask the question</p> <p>4 again.</p> <p>5 THE WITNESS: You're asking me a</p> <p>6 question, and I'm more than happy to answer,</p> <p>7 but you're not providing me with the foundation</p> <p>8 or the reference.</p> <p>9 BY MR. SCHNIEDERS:</p> <p>10 Q. Okay. Let me ask it this way: Do you</p> <p>11 believe that when there is a mesh complication that it</p> <p>12 is the result of physician error?</p> <p>13 MR. SNELL: Form, overbroad.</p> <p>14 Are you talking sling, prolapse or</p> <p>15 anything?</p> <p>16 MR. SCHNIEDERS: I'm asking a question.</p> <p>17 MR. SNELL: So overbroad.</p> <p>18 THE WITNESS: Would you be okay with</p> <p>19 substituting operator dependent for physician</p> <p>20 error? I don't know that I'm not comfortable</p> <p>21 with the term "physician error." I mean, I</p> <p>22 think it's operator dependent, rather than</p> <p>23 material related.</p> <p>24 BY MR. SCHNIEDERS:</p>
<p style="text-align: right;">Page 59</p> <p>1 MR. SNELL: You can go ahead and answer</p> <p>2 the question. Let me try and pull up the</p> <p>3 transcript.</p> <p>4 THE WITNESS: I don't have that in my</p> <p>5 working fund of knowledge. It's essentially on</p> <p>6 an annual basis and, again, understand that</p> <p>7 more the revisions that I do are not patients</p> <p>8 that I was the implanter so -- but it's about 1</p> <p>9 to 2%.</p> <p>10 BY MR. SCHNIEDERS:</p> <p>11 Q. One to 2% of your --</p> <p>12 A. Of those I implant, correct.</p> <p>13 Q. And I've seen you testify on this</p> <p>14 particular issue before, and you stated that it's your</p> <p>15 belief that it's physician error when there's a</p> <p>16 complication; is that correct?</p> <p>17 MR. SNELL: I'm going to have to object.</p> <p>18 I think you may have misstated his testimony.</p> <p>19 MR. SCHNIEDERS: Well, he can certainly</p> <p>20 tell me that, if that's the case.</p> <p>21 MR. SNELL: -- in its entirety. Why</p> <p>22 don't you show it to him then, because I don't</p> <p>23 know what you're talking about, to be honest</p> <p>24 with you.</p>	<p style="text-align: right;">Page 61</p> <p>1 Q. Okay. That's fair.</p> <p>2 So to put it in simpler terms, it's the result</p> <p>3 of something that was or was not done by the physician,</p> <p>4 not saying it was negligent or anything like that?</p> <p>5 A. I understand.</p> <p>6 Q. That was the variable, not the material,</p> <p>7 correct?</p> <p>8 MR. SNELL: Same objection, overbroad.</p> <p>9 THE WITNESS: So --</p> <p>10 MR. SNELL: Vague as to time and scope.</p> <p>11 Go ahead.</p> <p>12 THE WITNESS: So the background is</p> <p>13 simply, you know, you've got the surgeon,</p> <p>14 you've got the patient, and the patient</p> <p>15 certainly -- the risks for something like</p> <p>16 retention varies based upon the patient and</p> <p>17 related co-morbidities. Understand that pelvic</p> <p>18 floor disorders rarely exist in isolation;</p> <p>19 therefore, you can have stress leakage, you can</p> <p>20 also have bladder dysfunction, voiding</p> <p>21 difficulty. So -- and you can have stress</p> <p>22 leakage and prolapse. You can have stress</p> <p>23 leakage, prolapse and voiding dysfunction. You</p> <p>24 can have all three of them with pre-existing</p>

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<p>1 neurologic conditions, like Parkinson's,</p> <p>2 multiple sclerosis, diabetes.</p> <p>3 So understanding that you've got</p> <p>4 operator variables and then you have patient</p> <p>5 variables as well, and then you have</p> <p>6 technique-related specifics. So they can be</p> <p>7 any combination, you know, of the above. Most</p> <p>8 of them, in my experience and in my extensive</p> <p>9 review of the literature, relate to the ones</p> <p>10 other than the material itself.</p> <p>11 BY MR. SCHNIEDERS:</p> <p>12 Q. And is it your opinion, Doctor, that</p> <p>13 with regard to the Ethicon products that you are</p> <p>14 testifying as an expert in this litigation, that those</p> <p>15 products do not cause mesh complications?</p> <p>16 MR. SNELL: Form. Same objections as</p> <p>17 before.</p> <p>18 THE WITNESS: There are complications</p> <p>19 related to Gynemesh and prolapse, such as</p> <p>20 erosion, that obviously it's the material that</p> <p>21 has eroded, but it is my opinion, as stated in</p> <p>22 my report, that this is not inherent in the</p> <p>23 material itself.</p> <p>24 BY MR. SCHNIEDERS:</p>	<p>1 and I think the literature more than adequately</p> <p>2 supports that position.</p> <p>3 BY MR. SCHNIEDERS:</p> <p>4 Q. Doctor, when I say mesh complications,</p> <p>5 what does that mean?</p> <p>6 MR. SNELL: Form, calls for speculation.</p> <p>7 THE WITNESS: I don't know what you mean</p> <p>8 by that.</p> <p>9 BY MR. SCHNIEDERS:</p> <p>10 Q. What does it mean to you?</p> <p>11 A. What does mesh complications mean to me?</p> <p>12 I guess literally it means any adverse event that may</p> <p>13 be associated with mesh.</p> <p>14 Q. And what adverse events, in your mind,</p> <p>15 may be associated with mesh?</p> <p>16 A. Again, counselor, maybe I didn't make</p> <p>17 myself clear, given that it is impossible to separate</p> <p>18 out the other variables, operator dependent variables,</p> <p>19 patient related risk factors, general techniques</p> <p>20 regarding prolapse surgery, the risks seem to be</p> <p>21 similar across the board and independent of the</p> <p>22 specific techniques.</p> <p>23 Q. So when I asked you what mesh</p> <p>24 complication meant to you, you said it meant any</p>
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<p>1 Q. Okay. And explain that for me.</p> <p>2 A. Sure. I think I have explained it in my</p> <p>3 report quite extensively that, first of all, all</p> <p>4 patients who have prolapse have deficient tissue,</p> <p>5 nonfunctioning muscle and pre-existing issues that any</p> <p>6 of the surgical techniques that we employ in prolapse</p> <p>7 surgery come with inherent risks, and I think the</p> <p>8 literature is quite clear across thousands of studies</p> <p>9 involving tens of thousands of women that risks are</p> <p>10 related to surgery as a broad category and not</p> <p>11 specifically the Prolift or Gynemesh procedure. It's</p> <p>12 quite clear to me that it's very similar and sometimes</p> <p>13 lower than the baseline risk of surgery.</p> <p>14 Q. So in those women, erosion would have</p> <p>15 occurred no matter what you put in them, right?</p> <p>16 MR. SNELL: Objection, form.</p> <p>17 THE WITNESS: With the understanding</p> <p>18 that most prolapse surgeries involve either</p> <p>19 suture or synthetic grafts or biological grafts</p> <p>20 or combinations thereof, complications such as</p> <p>21 wound complications, I'll take mesh erosion is</p> <p>22 simply one type of wound complication, the</p> <p>23 complications occur equally whether it's</p> <p>24 sutures or biologic grafts or synthetic grafts,</p>	<p>1 adverse event that may be associated with mesh,</p> <p>2 correct?</p> <p>3 A. Yes, I'm just interpreting what you</p> <p>4 asked me.</p> <p>5 Q. That's what you said, those were your</p> <p>6 words, right?</p> <p>7 A. Those were my words.</p> <p>8 Q. Okay. And when I ask you what adverse</p> <p>9 events might be associated with mesh, your answer is</p> <p>10 there are none?</p> <p>11 A. That's not what I said, counselor. I</p> <p>12 gave you my answer.</p> <p>13 (Document marked for identification as</p> <p>14 Toggia Deposition Exhibit No. 3.)</p> <p>15 BY MR. SCHNIEDERS:</p> <p>16 Q. I'm going to show you what I've marked</p> <p>17 as Exhibit 3, which is a copy of your website's front</p> <p>18 page. It's several pages long because if you go on the</p> <p>19 right side of the second page, you'll see there's a</p> <p>20 section entitled "Questions About Vaginal Mesh?"</p> <p>21 Do you see that?</p> <p>22 A. I do.</p> <p>23 Q. Who wrote that?</p> <p>24 A. I would say I was probably the author of</p>

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<p style="text-align: right;">Page 66</p> <p>1 that.</p> <p>2 Q. Okay. And at the very beginning there,</p> <p>3 it's got a link to the position statement from</p> <p>4 AUGS/SUFU, correct?</p> <p>5 A. Correct.</p> <p>6 Q. But what I want to go to is down the</p> <p>7 second to last page, and just so everybody is aware,</p> <p>8 and you know this, Doctor, everybody else in this room</p> <p>9 might not, but there's a section where you click for</p> <p>10 more, and that's where the rest of this language comes</p> <p>11 from.</p> <p>12 Does that seem familiar with your website,</p> <p>13 Doctor?</p> <p>14 A. Correct.</p> <p>15 Q. So that's why it's several pages longer</p> <p>16 than the rest of it.</p> <p>17 But if you go to the last page that has words</p> <p>18 on it, in the second to last paragraph it says,</p> <p>19 "Urogynecology Associates maintains a large patient</p> <p>20 database of women in whom we have performed these</p> <p>21 procedures, and we are continually reviewing our</p> <p>22 results. Our physicians have been involved in clinical</p> <p>23 research in this area, and, in general, our data</p> <p>24 suggests a largely positive experience and high patient</p>	<p style="text-align: right;">Page 68</p> <p>1 A. That is correct.</p> <p>2 Q. And going on to the last paragraph right</p> <p>3 here it says, finally, our physicians -- just so we're</p> <p>4 clear, Doctor, it's you and one other partner right</p> <p>5 now, correct?</p> <p>6 A. That's correct.</p> <p>7 Q. "Finally, our physicians have extensive</p> <p>8 experience in the evaluation and management of women</p> <p>9 who have experienced complications from transvaginal</p> <p>10 mesh procedures, including the surgical revision or</p> <p>11 removal of such devices."</p> <p>12 Do you see that?</p> <p>13 A. I do.</p> <p>14 Q. When you say "complications from</p> <p>15 transvaginal mesh procedures," what do you mean when</p> <p>16 you write that?</p> <p>17 A. I mean that if a women previously</p> <p>18 underwent a transvaginal mesh procedure or really any</p> <p>19 kind of surgery for pelvic organ prolapse or</p> <p>20 incontinence, whether it involved sutures or mesh</p> <p>21 material, that we have experience in evaluating and</p> <p>22 treating those conditions.</p> <p>23 Q. So, as it sits here today with regard to</p> <p>24 the Ethicon products that you are opining about, the</p>
<p style="text-align: right;">Page 67</p> <p>1 satisfaction."</p> <p>2 Do you see that?</p> <p>3 A. I do.</p> <p>4 Q. This database, is that what you are</p> <p>5 discussing when you say that you review these things on</p> <p>6 a regular basis?</p> <p>7 A. Yes.</p> <p>8 Q. And did you think about putting your</p> <p>9 data into a form that you might be able to bring here</p> <p>10 today in order to support your opinions?</p> <p>11 A. No.</p> <p>12 Q. Why not?</p> <p>13 MR. SNELL: I'm going to object. I</p> <p>14 don't think it's actually called for, but go</p> <p>15 ahead.</p> <p>16 THE WITNESS: You know, I don't think</p> <p>17 that that would be something that would be --</p> <p>18 it's not something I could easily put together,</p> <p>19 you know, quickly.</p> <p>20 BY MR. SCHNIEDERS:</p> <p>21 Q. But you are able to look at it and tell</p> <p>22 patients that are coming into your office that the data</p> <p>23 suggests a largely positive experience and high patient</p> <p>24 satisfaction?</p>	<p style="text-align: right;">Page 69</p> <p>1 products themselves don't cause the complications, it's</p> <p>2 some mixture of the patient, the doctor and potentially</p> <p>3 some other variable, correct?</p> <p>4 MR. SNELL: Form.</p> <p>5 THE WITNESS: It's a combination of all</p> <p>6 those things. I mean, if you do surgery</p> <p>7 without suture, you can't have suture-related</p> <p>8 problems. If you do surgery with suture, if</p> <p>9 it's permanent suture, you know, you can have</p> <p>10 mesh -- excuse me -- you can have suture</p> <p>11 related complications or adverse consequences,</p> <p>12 as I've previously published. And if you do</p> <p>13 procedures with biological grafts or synthetic</p> <p>14 mesh materials, there is a, you know, baseline</p> <p>15 risk as it is laid out in our report of, you</p> <p>16 know, percentages of patients that might</p> <p>17 experience exposure of the material.</p> <p>18 BY MR. SCHNIEDERS:</p> <p>19 Q. If a woman came in to your office and</p> <p>20 had previously had a Ethicon product, whether it be</p> <p>21 Gynemesh PS or Prolift or TVT and they had a</p> <p>22 complication, immediately you would understand that it</p> <p>23 wasn't that product that caused the complication,</p> <p>24 correct?</p>

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<p>1 MR. SNELL: Objection, form, incomplete</p> <p>2 hypothetical, vague.</p> <p>3 THE WITNESS: I'm not sure that I</p> <p>4 understand the foundation. If somebody had a</p> <p>5 Prolift procedure and comes to my office with</p> <p>6 exposed mesh, it's going to be my assumption</p> <p>7 that it is the Prolift mesh that is what I'm</p> <p>8 seeing in the vagina.</p> <p>9 BY MR. SCHNIEDERS:</p> <p>10 Q. But it would be your assumption that the</p> <p>11 Prolift mesh didn't cause the problem, correct?</p> <p>12 MR. SNELL: Objection, same objection.</p> <p>13 THE WITNESS: Wound complications are</p> <p>14 caused by problems with wound healing.</p> <p>15 BY MR. SCHNIEDERS:</p> <p>16 Q. Not the mesh, correct?</p> <p>17 A. Not the mesh, correct.</p> <p>18 Q. Okay. Would your opinion be the same if</p> <p>19 it was a Boston Scientific product?</p> <p>20 A. Yes.</p> <p>21 Q. So you don't believe that Boston</p> <p>22 Scientific products can cause complications, the mesh</p> <p>23 itself?</p> <p>24 MR. SNELL: Form, overbroad.</p>	<p>1 erosion if mesh isn't part of the procedure, so</p> <p>2 in that context, mesh erosion necessitates</p> <p>3 previous placement of mesh.</p> <p>4 BY MR. SCHNIEDERS:</p> <p>5 Q. And in that context, does the mesh cause</p> <p>6 the erosion?</p> <p>7 MR. SNELL: Form, incomplete</p> <p>8 hypothetical.</p> <p>9 THE WITNESS: I think the opinion that I</p> <p>10 state in my report that the material itself</p> <p>11 does not cause the complication.</p> <p>12 BY MR. SCHNIEDERS:</p> <p>13 Q. Is there any mesh that causes that sort</p> <p>14 of complication that's on the market or has been taken</p> <p>15 off the market in the last ten years?</p> <p>16 MR. SNELL: Form, vague.</p> <p>17 THE WITNESS: I think my opinion is</p> <p>18 limited to, you know, the products being --</p> <p>19 what I prepared for and what I've written is</p> <p>20 specific to Prolift and Gynemesh PS. I'm happy</p> <p>21 to answer those questions as they relate to</p> <p>22 that.</p> <p>23 BY MR. SCHNIEDERS:</p> <p>24 Q. When you report an adverse event to the</p>
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<p>1 THE WITNESS: I think complications can</p> <p>2 occur in people who have undergone implantation</p> <p>3 with these materials. I think that the opinion</p> <p>4 that I have expressed in my report is that</p> <p>5 these are known complications that occur with</p> <p>6 all of our surgeries to similar degrees.</p> <p>7 BY MR. SCHNIEDERS:</p> <p>8 Q. And I guess that's my question. You're</p> <p>9 saying that these are known complications that can</p> <p>10 occur with these products, but you're saying that</p> <p>11 across the board it's not the product causing the</p> <p>12 complication, correct?</p> <p>13 A. It is not the product causing the</p> <p>14 complication, correct.</p> <p>15 Q. It's something else, it's a variable of</p> <p>16 either the physician, the patient or some combination</p> <p>17 of those two?</p> <p>18 MR. SNELL: Form.</p> <p>19 THE WITNESS: It's always a combination</p> <p>20 of everything.</p> <p>21 BY MR. SCHNIEDERS:</p> <p>22 Q. But not including the mesh?</p> <p>23 MR. SNELL: Same objection, form.</p> <p>24 THE WITNESS: You can't have mesh</p>	<p>1 FDA, you're able to give an opinion as to whether or</p> <p>2 not the product that you're reporting the adverse event</p> <p>3 on was the cause or was related, correct?</p> <p>4 A. Correct.</p> <p>5 Q. Okay. Every time you reported an</p> <p>6 Ethicon product to the FDA as an adverse event, you</p> <p>7 said it wasn't related, correct?</p> <p>8 MR. SNELL: Objection, lacks foundation.</p> <p>9 THE WITNESS: I don't recall ever saying</p> <p>10 that I was concerned that the material itself</p> <p>11 was the problem.</p> <p>12 BY MR. SCHNIEDERS:</p> <p>13 Q. What about when you reported an Apogee?</p> <p>14 A. Again, it could be patient selection, it</p> <p>15 could be patient risk factors, we usually report all</p> <p>16 those. You know, this was a smoker, obese patient who</p> <p>17 had previous surgery, you know. I mean, obviously, I</p> <p>18 don't identify the surgeon individually, but I will</p> <p>19 make comment whether they came locally, you know, from</p> <p>20 a local institution, whether they came from another</p> <p>21 state.</p> <p>22 Again, my role is not to pass any kind of</p> <p>23 judgment or make any kind of decision. I'm simply</p> <p>24 reporting what I'm finding, and I trust it to the FDA</p>

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<p style="text-align: right;">Page 74</p> <p>1 that they're collecting similar information, if it does 2 exist. So I'm simply reporting it in a non-judgmental 3 manner. I'm not offering an opinion to them as far as 4 what I think happened. 5 Q. Well, there's a subsection of the form 6 that allows for you to say it's related or not related, 7 correct? 8 MR. SNELL: Foundation. 9 THE WITNESS: I don't recall 10 specifically. It's been a number of years 11 since I've had to report something. I wouldn't 12 argue with you if you told me specifically that 13 there was an area that said it was related. 14 BY MR. SCHNIEDERS: 15 Q. It's been several years since you've 16 reported anything as an adverse event? 17 A. Two years, I would say. I can't give 18 you an independent recollection of the last time that I 19 reported something of that matter. 20 Q. When was your last mesh revision 21 surgery? 22 A. Maybe six months ago. 23 Q. You didn't report that as an adverse 24 event?</p>	<p style="text-align: right;">Page 76</p> <p>1 materials in that box and leave that with the court 2 reporter; is that fair, Doctor? 3 A. We will have copies -- I just want to 4 make sure that I have copies for further. 5 MR. SNELL: He is talking about after 6 the depositions. 7 MR. SCHNIEDERS: After tomorrow. 8 MR. SNELL: Yeah, that's fine. Just 9 make sure it gets back to Dr. Toggia. In TVT 10 last time he had an issue where -- 11 THE WITNESS: I didn't get the material 12 for four months. So, unfortunately, counselor, 13 prior experience has got my guard up, and I 14 mean no offense to you. 15 MR. SCHNIEDERS: That's fair, and, of 16 course, you know that has nothing to do with us 17 either. 18 THE WITNESS: I'm willing, but if I seem 19 hesitant or reluctant, once bitten, twice shy, 20 but I plan to be fully cooperative with 21 whatever the Court requests of me. 22 BY MR. SCHNIEDERS: 23 Q. And then Exhibit 5 I've actually 24 separately marked, this will not go in that box.</p>
<p style="text-align: right;">Page 75</p> <p>1 A. So my understanding is that the FDA 2 wants us to report on established products that were, 3 you know, approved for the indication. So if somebody 4 took a piece of Surgimesh or some Gortex mesh and had 5 used it vaginally in the repair, and there was erosion 6 of Gortex, which I think might have been the last one 7 that I saw, I would not have reported that to the FDA. 8 But if someone had a manufactured product, like 9 even things like NovaSure ablation or a device, you 10 know, Therma -- whatever the Thermachoice device is or 11 in this case Apogee Perigee, I report those type of 12 cases. 13 Q. When is the last time you did a revision 14 on a product like that? 15 A. Within the last year. I couldn't be 16 more specific than that. There are not very common 17 occurrences, fortunately, in our area. 18 (Document marked for identification as 19 Toggia Deposition Exhibit No. 4.) 20 BY MR. SCHNIEDERS: 21 Q. So housekeeping wise, I think I marked 22 as Exhibit 4 your box of your materials, and, as we 23 said off the record, we're going to -- after the 24 depositions tomorrow, you're going to put all your</p>	<p style="text-align: right;">Page 77</p> <p>1 (Document marked for identification as 2 Toggia Deposition Exhibit No. 5.) 3 BY MR. SCHNIEDERS: 4 Q. Exhibit 5 is your two invoices that you 5 brought here today as well, okay? 6 A. Sure, yes. 7 (Document marked for identification as 8 Toggia Deposition Exhibit No. 6.) 9 BY MR. SCHNIEDERS: 10 Q. Moving on to Exhibit 6, although I 11 believe you have a copy of it over there, Doctor, your 12 expert report. 13 A. Yes. 14 Q. Doctor, you are here today talking about 15 your general expert report regarding Gynemesh PS and 16 Prolift, correct? 17 A. That is correct. 18 Q. And this report, as we established 19 earlier, was issued -- 20 A. February 26, 2016. 21 Q. And that's your signature that appears 22 on Page 25? 23 A. That is my signature. 24 Q. Does this report contain all of your</p>

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<p>1 opinions you intend to offer in this matter?</p> <p>2 A. It does.</p> <p>3 Q. And, obviously, we've been doing it up</p> <p>4 to this point, but if you need that to refer or to</p> <p>5 answer any questions, clearly, go to it and use it.</p> <p>6 A. I appreciate that.</p> <p>7 Q. I have copies here, just to be -- make</p> <p>8 sure I've got everything, but I have copies here of the</p> <p>9 TVT expert report that was marked as part of the</p> <p>10 previous deposition.</p> <p>11 I assume nothing about your opinions has</p> <p>12 changed since the time of your deposition?</p> <p>13 A. That's correct. Nothing has changed.</p> <p>14 Q. I will not mark that.</p> <p>15 So I also have reliance list, which I think we</p> <p>16 established earlier in the deposition is actually the</p> <p>17 reliance list for your TVT report, and my confusion</p> <p>18 came from the fact that it has the same date at the</p> <p>19 very top there, and it didn't say TVT, so I think we</p> <p>20 have a copy of your reliance list for the Gynemesh and</p> <p>21 Prolift report somewhere around here, don't we?</p> <p>22 A. Right. It's not in the exhibit that you</p> <p>23 marked.</p> <p>24 MR. SNELL: You can give that to him and</p>	<p>1 A. That is correct.</p> <p>2 MR. SNELL: If I can say something, I</p> <p>3 just don't want there to be a misstatement on</p> <p>4 the record, and maybe I'm misremembering. I</p> <p>5 thought you had materials that Ostergard cited</p> <p>6 in his report too, or did you not have those?</p> <p>7 THE WITNESS: I showed this to you</p> <p>8 earlier, counselor. This is the -- these are</p> <p>9 the materials that Dr. Ostergard cited in his</p> <p>10 report that I don't believe were previously</p> <p>11 marked. Earlier you asked me about the</p> <p>12 educational materials that I did not have them</p> <p>13 in my personal records, but I did know that</p> <p>14 they were somewhere here.</p> <p>15 BY MR. SCHNIEDERS:</p> <p>16 Q. And that binder is part of what I'm</p> <p>17 considering to be Exhibit 4 that's going to go in the</p> <p>18 box afterwards, fair?</p> <p>19 A. That's fair.</p> <p>20 MR. SNELL: That makes sense.</p> <p>21 BY MR. SCHNIEDERS:</p> <p>22 Q. And both the deposition and the</p> <p>23 materials from the Ostergard deposition and expert</p> <p>24 report are not a part of your reliance list, as it sits</p>
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<p>1 mark that.</p> <p>2 THE WITNESS: It's been in my report. I</p> <p>3 don't know what was provided to you, but my</p> <p>4 report is accurate.</p> <p>5 MR. SNELL: You can give him that. That</p> <p>6 way he can mark it.</p> <p>7 MR. SCHNIEDERS: I'm just going to mark</p> <p>8 that reliance list.</p> <p>9 MR. SNELL: Sure.</p> <p>10 MR. SCHNIEDERS: I'm marking Exhibit 7</p> <p>11 as that reliance list.</p> <p>12 (Document marked for identification as</p> <p>13 Toggia Deposition Exhibit No. 7.)</p> <p>14 BY MR. SCHNIEDERS:</p> <p>15 Q. Doctor, what we've now marked as Exhibit</p> <p>16 7, I think we established earlier all the materials you</p> <p>17 brought today with you are somewhere on that list with</p> <p>18 the exception of one deposition that you've received I</p> <p>19 think since the TVT -- or I'm sorry -- since the actual</p> <p>20 report was issued; is that correct?</p> <p>21 A. Yes, correct.</p> <p>22 Q. And as we sit here today, you don't have</p> <p>23 any other materials to add to it or that you believe</p> <p>24 are missing, correct?</p>	<p>1 today, but you have reviewed them?</p> <p>2 A. Because they came after the fact.</p> <p>3 Q. Okay. But aside from the materials from</p> <p>4 the Ostergard expert report and that deposition,</p> <p>5 everything is on the reliance list?</p> <p>6 A. That's correct.</p> <p>7 Q. Doctor, who drafted the reliance list</p> <p>8 for you?</p> <p>9 A. The list itself was drafted by</p> <p>10 Mr. Snell's office with the understanding that much of</p> <p>11 the material were studies and reports that I provided</p> <p>12 to them.</p> <p>13 Q. Were there any materials that they</p> <p>14 provided to you that you did not ask for?</p> <p>15 A. My recollection is that there were</p> <p>16 studies that I was familiar with that I may not have</p> <p>17 had a hard copy of, and I received a hard copy from</p> <p>18 them, but, in general, you know, you're looking at how</p> <p>19 I spend many of my nights and weekends over the past 25</p> <p>20 years, the type of materials that I read. So much of</p> <p>21 this is stuff that I've been familiar with for decades</p> <p>22 or from whenever it was published.</p> <p>23 Q. So as I'm looking at your invoices, the</p> <p>24 last one was billed on February 29th of 2016, which was</p>

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<p>1 right about the same time, if not the same day --</p> <p>2 A. Correct.</p> <p>3 Q. -- that you issued your report.</p> <p>4 So does that invoice encompass all the time</p> <p>5 that you spent up to the time you issued your report?</p> <p>6 A. With regard to the general Prolift,</p> <p>7 Gynemesh report and the case specific reports, yes,</p> <p>8 separate from the TVT.</p> <p>9 Q. Okay. So are these invoices that I'm</p> <p>10 looking at that we've marked as Exhibit 5, do they not</p> <p>11 include your work on TVT?</p> <p>12 A. That's correct.</p> <p>13 Q. Okay. There are separate invoices for</p> <p>14 that?</p> <p>15 A. That's correct.</p> <p>16 Q. And so you're keeping track of your</p> <p>17 time, whether you believe you're working on the Prolift</p> <p>18 side of things or the TVT side of things?</p> <p>19 A. Separately, correct.</p> <p>20 Q. I think that here as of January 31st of</p> <p>21 this year, you had 12 hours billed at \$400 an hour, and</p> <p>22 that was to the Ethicon Gynecare mesh litigation MDL,</p> <p>23 and it says 200, although, obviously, that's not the</p> <p>24 right MDL.</p>	<p>1 A. I want to say maybe an additional 20</p> <p>2 hours.</p> <p>3 Q. And that goes to what my question was,</p> <p>4 and maybe I wasn't very clear, so I apologize. You</p> <p>5 issued your second invoice as of February 29th of 2016.</p> <p>6 Did that include -- because it says</p> <p>7 consultation fee, 2/1/16 through 2/29/16, did that</p> <p>8 include all the work that you had put in up until you</p> <p>9 signed your expert report?</p> <p>10 A. The question that you had asked me</p> <p>11 previously is what I billed them, and I've given you</p> <p>12 the information that I billed them. That would include</p> <p>13 all the work that I did up until the final date on that</p> <p>14 bill. Anything outstanding is subsequent to that date.</p> <p>15 Is that what you're asking.</p> <p>16 Q. Yeah. So this February 29, 2016 --</p> <p>17 A. There's no additional unbilled time for</p> <p>18 that time.</p> <p>19 Q. Okay. I apologize for being scattered</p> <p>20 on it. To make it clear --</p> <p>21 A. No, you were quite clear. You asked me</p> <p>22 what time I had billed and I answered what time I had</p> <p>23 billed. So I was clear on what you asked me,</p> <p>24 counselor.</p>
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<p>1 Does that look correct.</p> <p>2 A. Is it 2000? What's the --</p> <p>3 Q. Well, either way, but that's as of</p> <p>4 January 31st, that's the date that --</p> <p>5 A. Yes. The inclusive dates are on the</p> <p>6 list and you can see -- I mean, I know you weren't at</p> <p>7 the TVT deposition, but we switched -- I switched gears</p> <p>8 after that, correct. So I believe it's a total of</p> <p>9 about 47 hours that was billed by the end of February,</p> <p>10 if I'm not mistaken.</p> <p>11 Q. It's 35 on this one and then it was 12</p> <p>12 on this one, so 47 hours as of the time that you issued</p> <p>13 your report that you had spent working specific to</p> <p>14 these two products we're here today for?</p> <p>15 A. Mm-hmm.</p> <p>16 Q. Is that a yes?</p> <p>17 A. Excuse me, that I've billed for.</p> <p>18 Q. That you've billed for?</p> <p>19 A. Correct.</p> <p>20 Q. Okay. As we sit here, do you still have</p> <p>21 uninvoiced time?</p> <p>22 A. I do.</p> <p>23 Q. How much time would you estimate that</p> <p>24 you have that has not been billed?</p>	<p>1 Q. So then as of March, so from the date</p> <p>2 that you signed your expert report forward, you've done</p> <p>3 an additional 20 hours approximately?</p> <p>4 A. Approximately.</p> <p>5 Q. Did that include deposition preparation</p> <p>6 time with Mr. Snell?</p> <p>7 A. It will.</p> <p>8 Q. Did you prepare for today's deposition?</p> <p>9 A. Yes.</p> <p>10 Q. How long did you spend with Mr. Snell or</p> <p>11 any of his partners to prepare?</p> <p>12 A. Ninety minutes.</p> <p>13 Q. So then the other 18 and a half hours or</p> <p>14 so would have been spent reading literature?</p> <p>15 A. No. Again, not wanting to waste the</p> <p>16 Court's time, I wanted to read through the report and</p> <p>17 make some tabular notes, so when you asked me a</p> <p>18 specific question, I'd be able to find that information</p> <p>19 quickly, so reading, rereading, rechecking, summary</p> <p>20 type statistics. As I was provided, for example,</p> <p>21 Dr. Ostergard's deposition and materials, reviewing.</p> <p>22 Q. I think you testified to this, but just</p> <p>23 so we're clear, when you met with Mr. Snell and anyone</p> <p>24 else from his office to prepare, they didn't show you</p>

22 (Pages 82 to 85)

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<p style="text-align: right;">Page 86</p> <p>1 any documents?</p> <p>2 A. I'm not clear.</p> <p>3 Q. Did they show you any documents when you</p> <p>4 were preparing for your deposition?</p> <p>5 A. They provided me with Ostergard's.</p> <p>6 Q. But that's it?</p> <p>7 A. That's the example, yes.</p> <p>8 Q. Anything else?</p> <p>9 A. Specifically, no, not that I can think</p> <p>10 of.</p> <p>11 Q. Have you ever seen any internal Ethicon</p> <p>12 documents?</p> <p>13 A. I have seen Ethicon documents. I</p> <p>14 believe that was covered in the last TVT report. I do</p> <p>15 not think I've seen anything additionally since.</p> <p>16 Q. The last TVT deposition?</p> <p>17 A. Excuse me, the TVT deposition, correct.</p> <p>18 Q. So has the defendant ever shown you any</p> <p>19 internal documents?</p> <p>20 A. The ones that I just mentioned. There</p> <p>21 were documents provided -- there were documents of</p> <p>22 internal communication provided to me by Mr. Snell</p> <p>23 initially that were reviewed relevant to the TVT</p> <p>24 report. I mean, obviously, some of the information is</p>	<p style="text-align: right;">Page 88</p> <p>1 doesn't go out of its way to come up with new</p> <p>2 mechanisms to control a common function. So if the</p> <p>3 body already has a functioning mechanism for the</p> <p>4 control of urinary -- of urine, that's similar type</p> <p>5 physiologic mechanisms might exist for fecal control.</p> <p>6 So we were exploring the feasibility of that, and that</p> <p>7 has also been explored by other surgeons with other</p> <p>8 companies.</p> <p>9 Q. Doctor, would you say that, in your</p> <p>10 experience, Prolift and TVT have clearly shown that</p> <p>11 erosion occurs at the incision line all the time?</p> <p>12 MR. SNELL: Form.</p> <p>13 THE WITNESS: Can you repeat the</p> <p>14 question.</p> <p>15 BY MR. SCHNIEDERS:</p> <p>16 Q. Sure. Would you say that, in your</p> <p>17 experience, that Prolift and TVT clearly show that</p> <p>18 erosion occurs at the incision line all of the time?</p> <p>19 MR. SNELL: Objection.</p> <p>20 THE WITNESS: As a general rule, the</p> <p>21 exposure that I have seen and that I have read</p> <p>22 about tend to be in the incision line. Less</p> <p>23 commonly, you might see an erosion at other</p> <p>24 points of tension. Obviously, there are</p>
<p style="text-align: right;">Page 87</p> <p>1 relevant to the content today, but I've received no</p> <p>2 additional documents other than the ones that we listed</p> <p>3 for that report, and I believe they're listed on our</p> <p>4 reference list here as well.</p> <p>5 Q. Anything that you're talking about that</p> <p>6 you had seen, you would have -- you believed it was on</p> <p>7 your reliance list for the TVT report?</p> <p>8 A. I do believe, yes.</p> <p>9 Q. Doctor, earlier you mentioned a product</p> <p>10 called the Sphinx.</p> <p>11 Do you recall that?</p> <p>12 A. I do.</p> <p>13 Q. What was the Sphinx? Is it Sphinx or</p> <p>14 the Sphinx?</p> <p>15 A. I think the project was just generically</p> <p>16 called Sphinx, as a pun on the word sphincter, and I</p> <p>17 believe we covered that during the TVT deposition.</p> <p>18 Q. What is the Sphinx?</p> <p>19 A. The Sphinx is a large stone structure in</p> <p>20 Cairo, Egypt. Sphinx was a project that looked at --</p> <p>21 Sphinx was a project that looked at whether or not we</p> <p>22 could extrapolate the integral theory to the posterior</p> <p>23 compartments specifically for fecal continence. It's</p> <p>24 my belief, as it is the belief of others, that the body</p>	<p style="text-align: right;">Page 89</p> <p>1 probably situations where the vaginal</p> <p>2 epithelium was unintentionally breached, and so</p> <p>3 then you would have exposure of mesh that was</p> <p>4 subsequently discovered that likely was there</p> <p>5 initially.</p> <p>6 BY MR. SCHNIEDERS:</p> <p>7 Q. If there's more surface area of a sling</p> <p>8 that is directly below an incision, is there a higher</p> <p>9 risk of erosion?</p> <p>10 A. More surface area than what?</p> <p>11 Q. Than less surface area.</p> <p>12 MR. SNELL: Form.</p> <p>13 THE WITNESS: I'm not sure that I</p> <p>14 understand what you're asking me.</p> <p>15 BY MR. SCHNIEDERS:</p> <p>16 Q. Is it better to eliminate as much</p> <p>17 surface area of sling directly below an incision in</p> <p>18 order to keep a lower rate of erosion?</p> <p>19 A. I don't believe so.</p> <p>20 Q. Does a larger surface area of sling</p> <p>21 directly below an incision increase the risk of</p> <p>22 erosion?</p> <p>23 A. Not that I'm aware of.</p> <p>24 (Document marked for identification as</p>

23 (Pages 86 to 89)

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<p style="text-align: right;">Page 90</p> <p>1 Toggia Deposition Exhibit No. 8.)</p> <p>2 BY MR. SCHNIEDERS:</p> <p>3 Q. Let me show you what I've marked as</p> <p>4 Exhibit 8. This is an e-mail string from inside of</p> <p>5 Ethicon. At the very top you see that there's an</p> <p>6 e-mail from a gentleman named Gene Kammerer?</p> <p>7 A. I do.</p> <p>8 Q. Do you know Gene Kammerer?</p> <p>9 A. I do.</p> <p>10 Q. Who is Gene Kammerer?</p> <p>11 A. Gene Kammerer I believe was an engineer</p> <p>12 consultant that worked with the R&D team at Ethicon on</p> <p>13 some of their projects. He's one of the project people</p> <p>14 that I worked with directly, probably was my most</p> <p>15 direct contact regarding the Sphinx or PASS procedure</p> <p>16 as we were considering it.</p> <p>17 Q. And you see the subject he's responding</p> <p>18 to there says re: Dr. Toggia's comments on Sphinx and</p> <p>19 PASS.</p> <p>20 Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. And we don't need to go through</p> <p>23 that e-mail. You're welcome to look at it, if you</p> <p>24 like, but the very first e-mail is at the very bottom,</p>	<p style="text-align: right;">Page 92</p> <p>1 located very close to the skin. Therefore, a post anal</p> <p>2 sling will sit very close to the surface epithelium as</p> <p>3 well, and a crescent incision will significantly</p> <p>4 increase the surface area of sling directly beneath the</p> <p>5 incision and, therefore, the risk for erosion. A</p> <p>6 significant erosion rate will be the death of this</p> <p>7 procedure.</p> <p>8 Q. This procedure, as we stated earlier,</p> <p>9 never made it to market; it was abandoned before it got</p> <p>10 there, correct?</p> <p>11 A. I would like to think that it was placed</p> <p>12 on a shelf. Abandoned is kind of a cruel word for the</p> <p>13 parent of the concept.</p> <p>14 Q. Well, at any rate, it's not on the</p> <p>15 market currently?</p> <p>16 A. No. There are no sling based repairs on</p> <p>17 the market for this problem.</p> <p>18 Q. Okay. And were you being truthful when</p> <p>19 you told Mr. Kammerer that the surface area of sling</p> <p>20 that is directly beneath the incision would increase</p> <p>21 the rate of erosion?</p> <p>22 MR. SNELL: Objection, lacks foundation,</p> <p>23 assumes --</p> <p>24 THE WITNESS: I mean, this was my</p>
<p style="text-align: right;">Page 91</p> <p>1 and that's also from Mr. Kammerer, and on the second</p> <p>2 page it continues, "As you know I have been keeping a</p> <p>3 dialogue going with some of the advisory panel surgeons</p> <p>4 regarding our work and the concepts. Dr. Toggia has</p> <p>5 responded to the changes we made to the PASS concept</p> <p>6 and feels adamant that the 2 lateral incisions are</p> <p>7 crucial to its success. He has also provided some</p> <p>8 insight to the customer database which I haven't heard</p> <p>9 in our market research interviews. Here are some of</p> <p>10 his comments," and then you see what at least</p> <p>11 Mr. Kammerer is saying is a comment from you.</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. Why don't you read that first</p> <p>15 paragraph right there regarding the two?</p> <p>16 A. Regarding the 2 incisions versus a</p> <p>17 midline incision, as you know, there are many reasons</p> <p>18 why I feel that a single midline incision is a bad</p> <p>19 idea. Mostly, I am concerned about the erosion of the</p> <p>20 sling material through the perianal skin. Our</p> <p>21 experience with Prolift and TVT clearly show that</p> <p>22 erosions occur at the incision line all of the time,</p> <p>23 which is I think what I just stated to you. The</p> <p>24 perianal skin is very thin, and the sphincter is</p>	<p style="text-align: right;">Page 93</p> <p>1 theory, and I'm sorry, I mean, what you asked</p> <p>2 me earlier was -- I didn't hear you say below</p> <p>3 the incision. I simply heard you say below the</p> <p>4 epithelium. My point was at least in this</p> <p>5 location, you know, this is not the same</p> <p>6 location, by any means, compared to, say, the</p> <p>7 suburethral or the vagina but in basically the</p> <p>8 post anal area, it was at least my theory that</p> <p>9 we would be better off with separate lateral</p> <p>10 incisions as opposed to a contiguous incision.</p> <p>11 BY MR. SCHNIEDERS:</p> <p>12 Q. Would you agree with this statement that</p> <p>13 a significant erosion rate would be the death of the</p> <p>14 procedure?</p> <p>15 MR. SNELL: Form, lacks foundation.</p> <p>16 THE WITNESS: No. I think that with</p> <p>17 regard to this particular concept, which was</p> <p>18 the PASS procedure, that I was concerned that</p> <p>19 that would be a significant limitation.</p> <p>20 Obviously, I had no data because there was no</p> <p>21 data to support that, but I was -- I don't</p> <p>22 think you can extrapolate what I'm saying here</p> <p>23 to anything other than the concept of what we</p> <p>24 have here.</p>

24 (Pages 90 to 93)

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<p style="text-align: right;">Page 94</p> <p>1 BY MR. SCHNIEDERS:</p> <p>2 Q. What kind of mesh was used in the</p> <p>3 Sphinx?</p> <p>4 A. Well, to be determined. We tried a</p> <p>5 variety of materials. I can't tell you that we ever</p> <p>6 got to that, you know, to the specific platform.</p> <p>7 Q. Isn't it true that you started off with</p> <p>8 the concept of the TVT mesh?</p> <p>9 A. Well, we had to play around with</p> <p>10 something, and what was readily available to Ethicon</p> <p>11 and Ethicon engineers were the TVT material, and so we</p> <p>12 did utilize TVT passers and the TVT mesh to see if we</p> <p>13 could anatomically place that material within that</p> <p>14 space.</p> <p>15 Q. And that's the mesh you were using when</p> <p>16 you were concerned here in 2009 regarding erosions,</p> <p>17 correct?</p> <p>18 A. One had nothing to do with the other.</p> <p>19 It had to do more with the type of incision being made,</p> <p>20 which is different than the type of -- we don't make</p> <p>21 lateral incisions next to the urethra.</p> <p>22 Q. So you wanted to make a different type</p> <p>23 of incision, correct?</p> <p>24 A. Given that we were operating close to</p>	<p style="text-align: right;">Page 96</p> <p>1 verge. And rather than one contiguous incision, I was</p> <p>2 suggesting two smaller incisions.</p> <p>3 Q. Fair to say that you were attempting to</p> <p>4 decrease the surface area of sling that was directly</p> <p>5 beneath the incision, correct?</p> <p>6 MR. SNELL: Form.</p> <p>7 THE WITNESS: There were many different</p> <p>8 things that I was thinking about doing. And,</p> <p>9 again, that's a very different area, the</p> <p>10 concerns are somewhat different. The tension</p> <p>11 lines are different. We now have the added</p> <p>12 possibility of stool, you know, close to the</p> <p>13 incision. I was simply trying to move the</p> <p>14 incisions away from the anal verge, as I've</p> <p>15 already stated.</p> <p>16 BY MR. SCHNIEDERS:</p> <p>17 Q. And that's because your experience with</p> <p>18 Prolift and TVT clearly shows that the erosion occurs</p> <p>19 at the incision site all the time?</p> <p>20 A. No. It was for the reasons that I just</p> <p>21 mentioned. In my head, I was thinking I want to get</p> <p>22 these incisions away from the anal verge, away from the</p> <p>23 path of stool. I think that there's different surface</p> <p>24 tension forces next to the anus, and so I at least</p>
<p style="text-align: right;">Page 95</p> <p>1 the rectum where stool comes out of, you know, if I</p> <p>2 had -- you know, my concept was how can I locate the</p> <p>3 incisions a little bit away, away from the actual anal</p> <p>4 verge so that it's not in direct contact with the</p> <p>5 passage of stool. Additionally, considering the normal</p> <p>6 surface tension when a person sits down that would be</p> <p>7 placed on the perianal area, that's much more</p> <p>8 susceptible to say midline tension, we were looking at</p> <p>9 incisions that were non-midline, but, again, I don't</p> <p>10 think that this -- I don't think that I'm necessarily</p> <p>11 commenting on my concerns relative to the other</p> <p>12 procedures, but I was trying to use terms that they</p> <p>13 were familiar with based upon their other products.</p> <p>14 Q. Like erosion?</p> <p>15 A. I'm sorry.</p> <p>16 Q. Terms they were familiar with on their</p> <p>17 other products like erosion?</p> <p>18 A. No. I'm sorry, as far as the location</p> <p>19 of the incision. They were used to -- all of their</p> <p>20 sling products were done through a midline, vertical</p> <p>21 incision, and I was suggesting in this concept that the</p> <p>22 incisions be at a right angle to that, obviously in a</p> <p>23 different location, and I was trying to position -- I</p> <p>24 was trying to position the incisions away from the anal</p>	<p style="text-align: right;">Page 97</p> <p>1 wanted to start with the concept would it be feasible</p> <p>2 to place the incisions there.</p> <p>3 And they would say, well, why, why do you think</p> <p>4 that? And I would, again, try to communicate to them</p> <p>5 in their own language, and I would say, well, as you</p> <p>6 know, we were aware of circumstances where the slings</p> <p>7 are showing exposure, and, you know, the one factor at</p> <p>8 the time that was being considered was the location or</p> <p>9 type of incision.</p> <p>10 The French, when they did their TVM products,</p> <p>11 also were looking at transverse incisions as opposed to</p> <p>12 midline incisions.</p> <p>13 Q. Doctor, yes, no or you can't answer,</p> <p>14 larger surface area of sling directly beneath an</p> <p>15 incision increases the risk of erosion?</p> <p>16 MR. SNELL: Objection, asked and</p> <p>17 answered. You don't have to answer it yes, no</p> <p>18 or I don't know. You told him before.</p> <p>19 THE WITNESS: I've already stated my</p> <p>20 answer, counselor. I'm really trying not to be</p> <p>21 difficult. I honestly -- and I realize that</p> <p>22 you have no expertise in this area of the body,</p> <p>23 but there were unique challenges working near</p> <p>24 the rectum, and I was trying to address those,</p>

25 (Pages 94 to 97)

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<p>1 you know, again, just based on theory. There's</p> <p>2 no evidence that what I said would have borne</p> <p>3 out to be true. It may have turned out that a</p> <p>4 midline incision was perfectly feasible and/or</p> <p>5 easier. I was just starting with a slightly</p> <p>6 different concept for the reasons that I</p> <p>7 explained.</p> <p>8 In addition, there was another product</p> <p>9 in development for a similar indication, and I</p> <p>10 was trying to make this one different, you</p> <p>11 know, in its approach.</p> <p>12 BY MR. SCHNIEDERS:</p> <p>13 Q. So the reason you said the Sphinx at</p> <p>14 that time was because you were trying to differentiate</p> <p>15 the product and because you had a theory that</p> <p>16 potentially the surface area of the sling above the</p> <p>17 incision site could increase the risk of erosion,</p> <p>18 correct?</p> <p>19 MR. SNELL: Objection, misstates.</p> <p>20 THE WITNESS: One of a number -- again,</p> <p>21 I was trying to explore a unique concept that</p> <p>22 whether or not this would work to our</p> <p>23 advantage. You know, obviously we already had</p> <p>24 experience with midline incisions. In general,</p>	<p>1 again, I was trying to explain to them in terms that an</p> <p>2 engineer, who is familiar with the different product,</p> <p>3 would understand. But, obviously, I did not edit --</p> <p>4 write or edit this information.</p> <p>5 Q. Did you ever e-mail with Mr. Kammerer?</p> <p>6 A. Yes.</p> <p>7 Q. Are you able to testify this wasn't an</p> <p>8 e-mail that he had cut and pasted into this e-mail that</p> <p>9 he sent?</p> <p>10 A. I have no idea, sir.</p> <p>11 Q. And did you go to look in your own</p> <p>12 personal e-mails to see if you could find this one from</p> <p>13 2009?</p> <p>14 A. I no longer own -- I no longer have --</p> <p>15 that computer has been destroyed along with all of its</p> <p>16 material. I don't own the rights to this concept, so I</p> <p>17 was informed to discard all of that once the product</p> <p>18 was abandoned, as you so put it.</p> <p>19 Q. And you went through and cleaned out all</p> <p>20 of your e-mails and deleted all of them at that point?</p> <p>21 A. I deleted all of those e-mails and then</p> <p>22 when I wiped the hard drive on that computer, that just</p> <p>23 went wherever those bits go, yes.</p> <p>24 Q. Sure, sure. But there's a server</p>
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<p>1 they worked well. I was trying to come up with</p> <p>2 a more unique concept. You know, with two</p> <p>3 separate incisions, I was hoping that there</p> <p>4 would be no tension at the midpoint or directly</p> <p>5 beneath the incision line.</p> <p>6 BY MR. SCHNIEDERS:</p> <p>7 Q. But you weren't concerned about the</p> <p>8 amount of surface area of the sling beneath the</p> <p>9 incision, correct?</p> <p>10 A. I would say yes. I would say surface</p> <p>11 area was really not my concern but, again --</p> <p>12 Q. That's what you wrote down here?</p> <p>13 A. I understand.</p> <p>14 MR. SNELL: Actually, no, you're</p> <p>15 misstating. That is not his writing, so don't</p> <p>16 say he wrote that.</p> <p>17 THE WITNESS: That's true, good point.</p> <p>18 MR. SNELL: That lacks foundation.</p> <p>19 BY MR. SCHNIEDERS:</p> <p>20 Q. Are you saying that you didn't have a</p> <p>21 conversation about this topic with Gene Kammerer?</p> <p>22 A. No, no. I'm saying I had a</p> <p>23 conversation. I'm just saying I did not write these</p> <p>24 paragraphs, that these are not my words, okay. But,</p>	<p>1 somewhere where those e-mails probably exist; you know</p> <p>2 that?</p> <p>3 A. I don't know. I don't know. I honestly</p> <p>4 don't know.</p> <p>5 Q. What account would you have been using</p> <p>6 at that time to communicate with Mr. Kammerer?</p> <p>7 A. I honestly don't know.</p> <p>8 (Document marked for identification as</p> <p>9 Toglia Deposition Exhibit No. 9.)</p> <p>10 BY MR. SCHNIEDERS:</p> <p>11 Q. Let me mark as Exhibit 9 another e-mail</p> <p>12 from Mr. Kammerer.</p> <p>13 Is it possible that this e-mail address that</p> <p>14 you sent him an e-mail from, that's a Verizon address,</p> <p>15 is that the one you might have been using?</p> <p>16 A. It would seem to me that this would be</p> <p>17 the account that I e-mailed him from, correct.</p> <p>18 Q. Do you currently have the Verizon.net</p> <p>19 e-mail address?</p> <p>20 A. Yeah, and I would appreciate for privacy</p> <p>21 reasons if we didn't go into any more detail than that,</p> <p>22 given that this is a public document.</p> <p>23 Q. I'm assuming he's going to ask to have</p> <p>24 most of this sealed, to be honest.</p>

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<p>1 MR. SNELL: We'll go ahead and seal</p> <p>2 anything personal.</p> <p>3 THE WITNESS: I apologize, but there are</p> <p>4 concerns about identity theft and information</p> <p>5 that I have.</p> <p>6 BY MR. SCHNIEDERS:</p> <p>7 Q. I'm not going to e-mail you, I promise.</p> <p>8 A. Yes. So, again, this represents sort of</p> <p>9 my emotional response perhaps, and, again, remember as</p> <p>10 the parent to the concept, I was a little bit resistant</p> <p>11 to people wanting to change my concept because I</p> <p>12 thought that I had thought them out pretty clearly.</p> <p>13 Q. So, Dr. Toggia, if you go to the e-mail</p> <p>14 down below where you're actually e-mailing to</p> <p>15 Mr. Kammerer, and the subject is re: checking in,</p> <p>16 because I think if you go back there was originally an</p> <p>17 e-mail from you asking if the project was dormant?</p> <p>18 A. Sure.</p> <p>19 Q. But if you see here the third, and this</p> <p>20 is I think what you're talking about your emotional</p> <p>21 response to the way that they were approaching the</p> <p>22 project perhaps, but that third line starting</p> <p>23 "Ethicon," could you read that sentence or that</p> <p>24 paragraph there?</p>	<p>1 Q. Well, then what did you mean?</p> <p>2 A. I might have been referring specifically</p> <p>3 to the IVS Tunneller. You know, the IVS Tunneller,</p> <p>4 this was a concept that also involved the tunneling of</p> <p>5 mesh through several compartments over a long period of</p> <p>6 time, and the IVS Tunneller was also in its initial</p> <p>7 form both anterior and posteriorly involved similar</p> <p>8 type concepts. So now that I sort of reinvigorate my</p> <p>9 brain, I wouldn't be surprised if I'm referring to the</p> <p>10 IVS Tunneller in this statement.</p> <p>11 Q. You're referring to the IVS Tunneller</p> <p>12 with regard to Ethicon because it says Ethicon products</p> <p>13 right there?</p> <p>14 A. I didn't say that Ethicon's attempts, I</p> <p>15 just said attempts. The bottom line is that I don't</p> <p>16 recall, as I sit here, specifically what I was</p> <p>17 referring to in this e-mail. I'm sorry.</p> <p>18 Q. So it could be that you're talking about</p> <p>19 things like Gynemesh PS, correct?</p> <p>20 MR. SNELL: Objection, lacks foundation.</p> <p>21 THE WITNESS: I highly doubt this had</p> <p>22 anything to do with the Gynemesh PS.</p> <p>23 BY MR. SCHNIEDERS:</p> <p>24 Q. Could have been Prolift, right?</p>
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<p>1 A. I'm happy to. Let me just make sure I</p> <p>2 understand you clearly. You want me to begin reading</p> <p>3 the paragraph entitled "another key concept."</p> <p>4 Q. No. The one that starts with "Ethicon</p> <p>5 has enjoyed."</p> <p>6 A. Oh. Ethicon has enjoyed its greatest</p> <p>7 success with simple, straightforward thin sling - the</p> <p>8 TVT. Attempts to develop more comprehensive mesh</p> <p>9 solutions have far -- have not only been far less</p> <p>10 successful, but as a class have had serious</p> <p>11 complications and are rapidly falling out of favor.</p> <p>12 Q. What mesh solutions, comprehensive mesh</p> <p>13 solutions were you talking about there?</p> <p>14 A. I honestly don't know. This is from six</p> <p>15 years ago. These may have been other concept projects</p> <p>16 that -- at one point I sat down with them and we went</p> <p>17 over eight to ten new concepts for other projects</p> <p>18 within this sphere. Obviously, I would think in my</p> <p>19 mind if it was an existing project, I would have used</p> <p>20 the existing product's name.</p> <p>21 Q. How many comprehensive mesh solutions</p> <p>22 can you think of that have had serious complications?</p> <p>23 A. As a class, I don't know of any actually</p> <p>24 at this point.</p>	<p>1 MR. SNELL: Same objection.</p> <p>2 THE WITNESS: I honestly don't think it</p> <p>3 had to do with Prolift, in all honesty.</p> <p>4 BY MR. SCHNIEDERS:</p> <p>5 Q. Explain for the jury what the Tunneller</p> <p>6 does.</p> <p>7 A. Explain to you?</p> <p>8 Q. To the jury, you're talking to the jury</p> <p>9 right now.</p> <p>10 A. Am I talking to the jury right now? Is</p> <p>11 that who I'm talking to?</p> <p>12 MR. SNELL: You can just answer his</p> <p>13 questions to the best of your ability.</p> <p>14 Sometimes lawyers say things --</p> <p>15 THE WITNESS: I'm sorry. Got you. I</p> <p>16 mean, I'm just very literal, and I just want to</p> <p>17 make sure I don't misstate anything. Well, I</p> <p>18 mean, obviously, to deliver a product to its</p> <p>19 destination and whether it's laparoscopy or</p> <p>20 cannulas for TVT, cannulas for Prolift, you</p> <p>21 have to have a way to deliver the product to</p> <p>22 its final destination, and, again, the PASS</p> <p>23 concept involved placing a mesh sling below the</p> <p>24 anal sphincter and towing it up, if I remember</p>

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<p>1 correctly, through the obturator space as a</p> <p>2 point of exit.</p> <p>3 BY MR. SCHNIEDERS:</p> <p>4 Q. And what were the serious complications</p> <p>5 that were related to that?</p> <p>6 A. There weren't anything. The PASS</p> <p>7 concept never was done in a live person.</p> <p>8 Q. So, sitting here today, you can't think</p> <p>9 of any comprehensive mesh solutions that were developed</p> <p>10 as a class that have had serious complications and are</p> <p>11 rapidly falling out of favor that you might have been</p> <p>12 referencing in January of 2010?</p> <p>13 MR. SNELL: Objection, asked and</p> <p>14 answered.</p> <p>15 THE WITNESS: Yes, I mean, again, I</p> <p>16 cannot tell you what I specifically had in mind</p> <p>17 behind that statement. I was clearly, as you</p> <p>18 can see from the overall emotional tone of the</p> <p>19 letter, of the e-mail that I was being very</p> <p>20 emotionally resistant to the idea that we</p> <p>21 change anything. We hadn't even done anything</p> <p>22 with it yet. I wanted to test the original</p> <p>23 idea, as I had laid it forth to see what the</p> <p>24 feasibility was, and I was not open at the time</p>	<p>1 confidential. Let's mark the whole thing. For</p> <p>2 the purpose of whoever is going to be reviewing</p> <p>3 this on this issue, there are discussions about</p> <p>4 intellectual property concepts, thoughts by the</p> <p>5 doctor and what not which he has concerns about</p> <p>6 it falling into other people's hands. That is</p> <p>7 the basis and the purpose.</p> <p>8 THE WITNESS: Thank you.</p> <p>9 BY MR. SCHNIEDERS:</p> <p>10 Q. Doctor, are you doing any current</p> <p>11 research on polypropylene meshes?</p> <p>12 A. I mean, I consider the reviews that I do</p> <p>13 here where, you know, basically systematic review is a</p> <p>14 type of, you know, research project. In terms of --</p> <p>15 I'm not currently engaged in any clinical trials of</p> <p>16 that material.</p> <p>17 Q. Are you engaged in any attempts to</p> <p>18 publish any retrospective data or anything like that?</p> <p>19 A. My current role in that arena is that,</p> <p>20 you know, since I serve as an editor of two journals,</p> <p>21 my energy is spent actually reviewing studies and</p> <p>22 manuscripts submitted for publications, much of which</p> <p>23 is on the subject matter that we're discussing today,</p> <p>24 but I have no -- I have nothing pending to be</p>
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<p>1 to making changes.</p> <p>2 BY MR. SCHNIEDERS:</p> <p>3 Q. But sitting here today, you're sure that</p> <p>4 it's not Prolift that you were talking about?</p> <p>5 A. I don't recall it as being Prolift at</p> <p>6 the time, no.</p> <p>7 Q. And you're sure it's not Gynemesh PS</p> <p>8 that you're talking about?</p> <p>9 A. You know, I think I would have listed it</p> <p>10 by name. I listed their success by name. I think if I</p> <p>11 had a specific concern, I would have listed that as</p> <p>12 well.</p> <p>13 Q. You didn't mention Tunneller there, did</p> <p>14 you?</p> <p>15 A. No. I was talking about just the</p> <p>16 overall where we were conceptually, you know, at the</p> <p>17 time.</p> <p>18 MR. SCHNIEDERS: Maybe now is a good</p> <p>19 time to take a break.</p> <p>20 (Brief recess taken at 3:27 p.m.)</p> <p>21 (Deposition resumes at 3:38 p.m.)</p> <p>22 MR. SCHNIEDERS: We're back after a</p> <p>23 short break.</p> <p>24 MR. SNELL: Let's mark that last portion</p>	<p>1 published.</p> <p>2 Q. Have you ever written anything on the</p> <p>3 Burch procedure?</p> <p>4 MR. SNELL: Form.</p> <p>5 THE WITNESS: There may be mention in a</p> <p>6 book chapter, but I have not published on my</p> <p>7 personal experience with that procedure</p> <p>8 independent from a more general discussion.</p> <p>9 BY MR. SCHNIEDERS:</p> <p>10 Q. Have you ever written anything on</p> <p>11 biologic tissue slings?</p> <p>12 A. I have not.</p> <p>13 Q. You would agree that you're not an</p> <p>14 academic physician, correct?</p> <p>15 MR. SNELL: Form.</p> <p>16 THE WITNESS: I would not agree with</p> <p>17 that, no.</p> <p>18 BY MR. SCHNIEDERS:</p> <p>19 Q. Explain, please.</p> <p>20 A. Much of the work that I do is equivalent</p> <p>21 to what you do in academics. I was previously employed</p> <p>22 at an academic institution. I'm simply not employed by</p> <p>23 an academic institution. Obviously, I have</p> <p>24 appointments at an academic institution. Our current</p>

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<p>1 institution involves -- does have a residency, so I am 2 directly involved in teaching and the creation of 3 academic curriculum, resident education, resident 4 teaching. I do speak nationally in postgraduate 5 medical educations through venues such as AUGS, Society 6 of Gynecologic Surgeons. Those are academic endeavors. 7 Q. But you also have a private clinical 8 practice, correct? 9 A. Correct. 10 Q. So insofar as you are a private clinical 11 physician, in that portion of your life, that would not 12 be academic medicine, correct? 13 MR. SNELL: Objection. 14 THE WITNESS: I disagree. Again, before 15 I came here today, I was in the operating room 16 in my private practice. I had a resident with 17 me and a medical student with me. That is 18 academic in nature. We are discussing and 19 teaching. So it's all of the above. 20 BY MR. SCHNIEDERS: 21 Q. I may have asked this before, so forgive 22 me if I have. Are you currently under contract as a 23 consultant for any pharmaceutical or device company? 24 A. You did not ask that before. I</p>	<p>1 general rule, my involvement in the past several years 2 has been fairly minimal. 3 Q. You would agree that less rigidity with 4 regard to mesh is better, correct? 5 MR. SNELL: Form, overbroad, lacks 6 foundation. 7 THE WITNESS: I would not agree. 8 BY MR. SCHNIEDERS: 9 Q. Okay. Explain to me why not. 10 A. I'm not sure what the foundation is that 11 you're asking me. Less better for what? 12 Q. Less likely to cause or impair -- strike 13 that. 14 Less likely to impair sexual function? 15 MR. SNELL: Same objection, incomplete 16 hypothetical. 17 THE WITNESS: Yeah, it's more 18 complicated than that, counselor. Please keep 19 in mind that we don't have any cutoffs or 20 agreements, there are no expert consensus as 21 far as what's lightweight, what's not 22 lightweight, what's rigid, what's less rigid, 23 you know. These are just sort of a continuum 24 of ideas. You know, everything is relative.</p>
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<p>1 currently consult with a pharmaceutical company. I had 2 a consulting -- an active consultant agreement with a 3 medical device company that if we wait another week 4 will no longer exist. 5 Q. So would that be AMS? 6 A. That would be, very good. 7 Q. And who is the pharmaceutical company 8 you consult with currently? 9 A. So it would be Astellas Pharma whom I've 10 consult with since 1994, I believe, unrelated to what 11 we're discussing today. 12 Q. And would that be the longest standing 13 relationship you have in consulting with a 14 pharmaceutical or a device company? 15 A. I believe so. 16 Q. Have you continuously worked for 17 Astellas since 1994? 18 A. I have never worked for Astellas. 19 Q. Point taken. Have you continuously 20 worked with Astellas since 1994? 21 A. You know, intermittent relationship. 22 There are periods of time, different cycles of the 23 economy where they are more interested, less 24 interested. It varies widely. I would say, as a</p>	<p>1 You know, is this lightweight, well, it might 2 be lighter than something previously, not as 3 light as something later. But, in general, my 4 objection is that we don't have cutoffs, no one 5 has ever published, you know, this is heavy, 6 this is light. There's no expert consensus. 7 People do throw around the terms relatively, 8 this is lighter weight mesh, this is 9 lightweight, but I don't know what the cutoffs 10 are, and the same would apply to rigidity. 11 Q. So there are cutoffs, you just don't 12 know what they are? 13 MR. SNELL: Objection. 14 THE WITNESS: If I don't know -- if I 15 don't know what they are, how would I know that 16 there were cutoffs? 17 BY MR. SCHNIEDERS: 18 Q. You said but I don't know what the 19 cutoffs are, and the same would apply to rigidity. 20 That implies that there are cutoffs somewhere, right? 21 MR. SNELL: I'm going to object. 22 THE WITNESS: No. 23 MR. SNELL: Hold on. You have to let me 24 object. You're actually misstating his</p>

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<p>1 testimony. His testimony he did say there is</p> <p>2 no cutoff.</p> <p>3 MR. SCHNIEDERS: I'm again going to read</p> <p>4 because I don't need you to speak for the</p> <p>5 witness.</p> <p>6 MR. SNELL: I'm not speaking, but you</p> <p>7 are misstating his testimony --</p> <p>8 MR. SCHNIEDERS: I'm reading from it</p> <p>9 right here.</p> <p>10 MR. SNELL: His answer was 21 lines</p> <p>11 long.</p> <p>12 MR. SCHNIEDERS: He said I don't know</p> <p>13 what the cutoffs are and the same would apply</p> <p>14 to rigidity.</p> <p>15 MR. SNELL: No, his answer was 20 lines</p> <p>16 longer than the little thing you pulled out of</p> <p>17 there.</p> <p>18 MR. SCHNIEDERS: Whatever.</p> <p>19 BY MR. SCHNIEDERS:</p> <p>20 Q. Are there cutoffs?</p> <p>21 A. There are currently no established</p> <p>22 cutoffs, there are no definitions, and there is no</p> <p>23 expert consensus.</p> <p>24 Q. But, theoretically, there are cutoffs</p>	<p>1 A. No, I have not.</p> <p>2 Q. Did you go to them and have any input in</p> <p>3 their position statement regarding vaginal mesh?</p> <p>4 A. I did not have any direct input into</p> <p>5 that statement.</p> <p>6 Q. Did you ever review a draft of that</p> <p>7 statement?</p> <p>8 A. I don't believe that I reviewed a draft</p> <p>9 of that statement.</p> <p>10 Q. Were you ever circulated a draft of that</p> <p>11 statement?</p> <p>12 A. I might have been circulated a draft of</p> <p>13 that statement. I don't independently recall that.</p> <p>14 Q. And not to -- honestly not to make you</p> <p>15 uncomfortable, but had you received a draft of that</p> <p>16 statement, would that have been to that Verizon e-mail</p> <p>17 address?</p> <p>18 MR. SNELL: Objection.</p> <p>19 THE WITNESS: I don't know. I don't</p> <p>20 know. That would be one of the more common</p> <p>21 addresses that I might receive material, but I</p> <p>22 didn't receive it.</p> <p>23 BY MR. SCHNIEDERS:</p> <p>24 Q. You didn't receive it, or you don't know</p>
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<p>1 somewhere, right?</p> <p>2 MR. SNELL: Form, hypothetical.</p> <p>3 THE WITNESS: No.</p> <p>4 BY MR. SCHNIEDERS:</p> <p>5 Q. No?</p> <p>6 A. There are no established, universally</p> <p>7 accepted definitions, cutoffs, consensus of opinion.</p> <p>8 Q. Doctor, listen to my question. I said</p> <p>9 theoretically, there are cutoffs. I didn't say they</p> <p>10 were established, universally accepted cutoffs. I said</p> <p>11 theoretically there would be cutoffs, right?</p> <p>12 MR. SNELL: Objection, vague, calls for</p> <p>13 speculation.</p> <p>14 THE WITNESS: I don't know how further</p> <p>15 to answer that. I'm sorry.</p> <p>16 BY MR. SCHNIEDERS:</p> <p>17 Q. Why hasn't AUGS filed a consensus</p> <p>18 statement on what levels of rigidity are acceptable?</p> <p>19 A. I can't answer that question. I can't</p> <p>20 speak for AUGS.</p> <p>21 Q. Are you a member of that society?</p> <p>22 A. Yes.</p> <p>23 Q. Have you ever gone to them and said why</p> <p>24 don't we put out a consensus statement on this?</p>	<p>1 if you received it?</p> <p>2 A. I think it's the same thing. I do not</p> <p>3 recall that I have ever received a draft, to the best</p> <p>4 of my knowledge, of that statement, of the proposed</p> <p>5 statement.</p> <p>6 Q. Sorry didn't mean to interrupt.</p> <p>7 Do you know who the authors are of that</p> <p>8 statement?</p> <p>9 A. I do.</p> <p>10 Q. Do you know them personally?</p> <p>11 A. I do.</p> <p>12 Q. Do you consider yourself to be friends</p> <p>13 with those gentlemen?</p> <p>14 A. They are colleagues of mine.</p> <p>15 Q. Are they people you would see socially</p> <p>16 as well or just professionally?</p> <p>17 A. I think those lines are blurred in my</p> <p>18 area, as I'm sure they are in yours. You know, we have</p> <p>19 social events at our academic meetings, our scientific</p> <p>20 meetings. I don't believe I was in any of their</p> <p>21 wedding parties or went on vacation or sat in a Jacuzzi</p> <p>22 with any of them, but I would say, certainly, you know,</p> <p>23 I think it would be accurate to say that we have</p> <p>24 collegial relationships that are both social and</p>

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<p>1 academic.</p> <p>2 Q. Have you ever discussed authoring</p> <p>3 anything with any of them?</p> <p>4 A. I would have to look at the</p> <p>5 comprehensive list of the people on that if you want to</p> <p>6 share that with me.</p> <p>7 Q. We can cover that in a moment.</p> <p>8 A. Yeah.</p> <p>9 Q. You are not an expert in chemical</p> <p>10 engineering, correct?</p> <p>11 MR. SNELL: Form. This is covered in</p> <p>12 the earlier deposition.</p> <p>13 MR. SCHNIEDERS: And I am aware and</p> <p>14 that's why I'm asking it.</p> <p>15 BY MR. SCHNIEDERS:</p> <p>16 Q. Do you hold yourself out as an expert in</p> <p>17 chemical engineering?</p> <p>18 A. I think -- no, I don't hold myself out</p> <p>19 in a general sense in chemical engineering. I think I</p> <p>20 have expertise in this particular arena in front of any</p> <p>21 audience that I might be asked to participate as it</p> <p>22 relates to polypropylene mesh being used for its</p> <p>23 intended purpose.</p> <p>24 Q. You're not an expert in pathology,</p>	<p>1 in-depth level of knowledge than I.</p> <p>2 BY MR. SCHNIEDERS:</p> <p>3 Q. You agree you're not an expert in</p> <p>4 polymer chemistry, correct?</p> <p>5 MR. SNELL: Objection, asked and</p> <p>6 answered in earlier deposition.</p> <p>7 THE WITNESS: I think relative to the</p> <p>8 topic at hand, I would be considered by many to</p> <p>9 possess expertise in polymer chemistry.</p> <p>10 BY MR. SCHNIEDERS:</p> <p>11 Q. Relative to a jury, but not relative to</p> <p>12 a polymer chemist, correct?</p> <p>13 MR. SNELL: Same objections.</p> <p>14 THE WITNESS: You know, in terms of the</p> <p>15 application of this material within the human</p> <p>16 body, I've got a pretty good understanding of</p> <p>17 the working of polymer, yes. I have a degree</p> <p>18 in biochemistry. I've been reviewing this</p> <p>19 material extensively. I am certainly reading</p> <p>20 materials that are beyond what the average</p> <p>21 gynecologist or even urogynecologist female</p> <p>22 pelvic medicine or urologist would have</p> <p>23 reviewed.</p> <p>24 BY MR. SCHNIEDERS:</p>
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<p>1 correct?</p> <p>2 MR. SNELL: Objection.</p> <p>3 THE WITNESS: I'm -- I don't have any</p> <p>4 certification in pathology. I have certainly</p> <p>5 an in-depth knowledge and, again, you know, if</p> <p>6 we were to go to the Villanova game together,</p> <p>7 I'd probably know more than the majority of</p> <p>8 people at that game.</p> <p>9 BY MR. SCHNIEDERS:</p> <p>10 Q. But you would defer to a pathologist,</p> <p>11 correct?</p> <p>12 A. I don't know what you mean by "defer."</p> <p>13 I mean, if we had a disagreement, I wouldn't stand up</p> <p>14 and say you're a pathologist, you're absolutely right.</p> <p>15 No, I wouldn't defer in that regard.</p> <p>16 Q. So you believe that you have an equal</p> <p>17 expertise as a pathologist?</p> <p>18 A. I don't know where you're getting this</p> <p>19 from. I never made that statement.</p> <p>20 Q. You would agree that a pathologist has a</p> <p>21 greater expertise in pathology than you do?</p> <p>22 MR. SNELL: Form.</p> <p>23 THE WITNESS: Yes, I would say, in a</p> <p>24 general sense, a pathologist has a more</p>	<p>1 Q. When was that degree in biochemistry?</p> <p>2 A. 1985.</p> <p>3 Q. And when is the last class you took in</p> <p>4 biochemistry?</p> <p>5 A. Well, I mean, I'm constantly reading</p> <p>6 material. Obviously at this stage of the game I don't</p> <p>7 pay to enroll in college courses, but my -- you know,</p> <p>8 foundation of my knowledge did not end when I graduated</p> <p>9 from college.</p> <p>10 Q. When is the last class you took in</p> <p>11 biochemistry?</p> <p>12 A. I took a class in medical school in</p> <p>13 biochemistry.</p> <p>14 Q. About what year would that have been?</p> <p>15 A. That would have been 1986, '87.</p> <p>16 Q. You've never done bench research on</p> <p>17 polypropylene, correct?</p> <p>18 A. I have not.</p> <p>19 Q. You've never done lab research on</p> <p>20 polypropylene, correct?</p> <p>21 A. I have not.</p> <p>22 Q. You've never done any sort of</p> <p>23 pathological analysis on explanted polypropylene, have</p> <p>24 you?</p>

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<p style="text-align: right;">Page 122</p> <p>1 MR. SNELL: Form.</p> <p>2 THE WITNESS: I have not. Understand</p> <p>3 that I've done lab work as it pertains to my</p> <p>4 consultation with polypropylene products in</p> <p>5 medical, you know -- in the medical arena.</p> <p>6 BY MR. SCHNIEDERS:</p> <p>7 Q. When you explant mesh, what do you do</p> <p>8 with that mesh?</p> <p>9 A. The majority, depending upon -- you</p> <p>10 know, depending upon the situation, the majority of</p> <p>11 that material is sent to pathology for identification</p> <p>12 and labeling.</p> <p>13 Q. Okay. You don't do that yourself, you</p> <p>14 send it to a pathologist?</p> <p>15 A. Well, I'm operating on a patient, so I</p> <p>16 can't do both things, so I will send that to the</p> <p>17 pathologist.</p> <p>18 Q. Could you?</p> <p>19 A. Could I what?</p> <p>20 Q. Could you do what the pathologist does?</p> <p>21 A. Given that what the pathologist does is</p> <p>22 typically measure the dimensions of the material and</p> <p>23 simply reports that I have in front of me a 2 by 1</p> <p>24 centimeter piece of blue mesh, that I can do, correct.</p>	<p style="text-align: right;">Page 124</p> <p>1 correct?</p> <p>2 A. I am not, no.</p> <p>3 Q. I think we're going to get sideways</p> <p>4 here. You are not an expert on the design of medical</p> <p>5 devices, correct?</p> <p>6 MR. SNELL: Objection, covered in his</p> <p>7 first deposition extensively.</p> <p>8 THE WITNESS: I have worked on the</p> <p>9 design of medical devices. I have worked on</p> <p>10 the design and redesign of existing devices, as</p> <p>11 well as the device -- the medical device that</p> <p>12 we referred to earlier as the PASS device.</p> <p>13 BY MR. SCHNIEDERS:</p> <p>14 Q. And have you ever designed a device that</p> <p>15 made it to market?</p> <p>16 A. I have not.</p> <p>17 Q. I don't say that to cruel.</p> <p>18 A. No, I apologize. I had -- and, again,</p> <p>19 I'm a relatively humble person. I had extensive input</p> <p>20 into the design of the TVT Exact, which is currently on</p> <p>21 the market.</p> <p>22 Q. You had extensive input into the design</p> <p>23 before it went to market?</p> <p>24 A. Correct.</p>
<p style="text-align: right;">Page 123</p> <p>1 I can't tell you that in the medical world that there's</p> <p>2 any further analysis being done routinely.</p> <p>3 Q. You've never published any opinion that</p> <p>4 polypropylene does not cause a foreign body reaction,</p> <p>5 correct?</p> <p>6 A. Well, that's a double negative so -- and</p> <p>7 I do want to answer you accurately, so if you can</p> <p>8 restate that question without a double negative, I</p> <p>9 would appreciate it.</p> <p>10 Q. Have you ever published an opinion that</p> <p>11 polypropylene does not cause a foreign body reaction?</p> <p>12 A. Of course, polypropylene causes a</p> <p>13 foreign body reaction. Any foreign material implanted</p> <p>14 in the body will cause a foreign body reaction. That's</p> <p>15 what foreign body reaction is by definition.</p> <p>16 Q. You are not an expert on warnings,</p> <p>17 correct?</p> <p>18 MR. SNELL: Objection.</p> <p>19 THE WITNESS: I don't hold myself out to</p> <p>20 offer an expert opinion on warnings, although I</p> <p>21 have, you know, ample experience in, you know,</p> <p>22 reading about them and reading those materials.</p> <p>23 BY MR. SCHNIEDERS:</p> <p>24 Q. You're not a biomechanical engineer,</p>	<p style="text-align: right;">Page 125</p> <p>1 Q. Do you know what standards a</p> <p>2 manufacturer must follow in designing mesh products?</p> <p>3 A. I have a general awareness, a general</p> <p>4 awareness only.</p> <p>5 Q. But you couldn't cite us CFRs or</p> <p>6 statutes or anything like that, correct?</p> <p>7 A. I couldn't cite it, no.</p> <p>8 Q. Have you ever seen the statutes that</p> <p>9 relate to the responsibilities a manufacturer holds in</p> <p>10 designing a product?</p> <p>11 A. I don't recall, no.</p> <p>12 Q. Have you ever reviewed any of Ethicon's</p> <p>13 standard operating procedures relating to design?</p> <p>14 A. I do not believe so.</p> <p>15 Q. Do you know what a clinical expert</p> <p>16 report is?</p> <p>17 A. I believe this is the second one that</p> <p>18 I've issued in this arena, if I'm not mistaken. Is</p> <p>19 this what we're referring to?</p> <p>20 Q. What you've issued is a clinical expert</p> <p>21 report, that's your definition of it?</p> <p>22 A. Yes.</p> <p>23 Q. Do you know what a design history file</p> <p>24 is?</p>

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<p>1 A. In a general sense.</p> <p>2 Q. What is it?</p> <p>3 A. You know, when a manufacturer sets out</p> <p>4 to design a product, they would keep track of the</p> <p>5 history of that development and they would keep track</p> <p>6 of the communications between the different parties and</p> <p>7 the steps along that -- along that design.</p> <p>8 Q. All right, Doctor. So earlier we were</p> <p>9 talking about two days that you put in the Gynemesh PS</p> <p>10 on your operating days.</p> <p>11 What days are your operating days currently?</p> <p>12 A. How is this relevant to the testimony</p> <p>13 that I'm giving? I operate two days a week. Is that</p> <p>14 not sufficient information?</p> <p>15 Q. If you really don't want me to know what</p> <p>16 day, it's fine.</p> <p>17 A. Yes, thank you.</p> <p>18 Q. Two days a week?</p> <p>19 A. Correct.</p> <p>20 Q. And that's every week?</p> <p>21 A. Correct.</p> <p>22 Q. And how many surgeries do you do on</p> <p>23 those two days, typically?</p> <p>24 A. Sure, I previously answered that on</p>	<p>1 that you perform weekly, how many of those surgeries</p> <p>2 are likely to be Gynemesh PS?</p> <p>3 A. I didn't say I did 12 surgeries a week,</p> <p>4 for clarification. I said I did between six and eight</p> <p>5 procedures a week.</p> <p>6 Q. Oh, I thought that was per day.</p> <p>7 A. No, I'm sorry.</p> <p>8 Q. Okay. Six to eight per week?</p> <p>9 A. Correct.</p> <p>10 Q. So spread out over the two days?</p> <p>11 A. Correct, right.</p> <p>12 Q. And of those six to eight, how many are</p> <p>13 Gynemesh PS, typically?</p> <p>14 A. I would say it may range from two to</p> <p>15 four.</p> <p>16 Q. And with the understanding that,</p> <p>17 typically, it's going to be TVT Exact, how many are</p> <p>18 TVT?</p> <p>19 A. Again, I would say as an average range</p> <p>20 two to four, it could be five. It could be four to</p> <p>21 five in a single day.</p> <p>22 Q. So these are procedures that on a weekly</p> <p>23 basis you are discussing with patients and then</p> <p>24 performing, correct?</p>
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<p>1 average, I'll do between six and eight procedures, and</p> <p>2 they are virtually all related to pelvic floor</p> <p>3 disorders.</p> <p>4 Q. Are there any surgeries that you're</p> <p>5 doing currently that are not related to pelvic floor</p> <p>6 disorders?</p> <p>7 A. There may be some surgeries that are</p> <p>8 more general gynecology in nature. For example, if a</p> <p>9 woman is sent to me with prolapse and she tells me she</p> <p>10 has bleeding, I may first have to do a D&C or a biopsy</p> <p>11 or some other general thing prior to completing the</p> <p>12 treatment for the prolapse. So I would say it's within</p> <p>13 the sphere of gynecologic surgery and urogynecologic</p> <p>14 surgery.</p> <p>15 Q. So vast majority of your procedures</p> <p>16 currently are going to be a TVT product or the Gynemesh</p> <p>17 PS, correct?</p> <p>18 A. No. The vast majority of my procedures</p> <p>19 are prolapse and incontinence. Procedures, the</p> <p>20 prolapse procedures could be native tissue plication,</p> <p>21 obliterative procedures, Gynemesh or sacrocolpopexy</p> <p>22 procedures. The majority of my incontinence procedures</p> <p>23 are retropubic TVT procedures, specifically TVT Exact.</p> <p>24 Q. So out of approximately 12 surgeries</p>	<p>1 A. I would say on a daily basis, whether</p> <p>2 it's in the office or in the operating room, I am in</p> <p>3 constant, you know, dialogue, examinations that would</p> <p>4 involve these type of products, absolutely.</p> <p>5 Q. So specific, and, you know, I guess we</p> <p>6 haven't said this, but is the Prolift on the market</p> <p>7 right now?</p> <p>8 A. It is not.</p> <p>9 Q. Why is that?</p> <p>10 A. The manufacturer decided to withdraw the</p> <p>11 product from the market.</p> <p>12 Q. Was there FDA action that preceded that?</p> <p>13 A. It's my understanding that the FDA</p> <p>14 wanted to require very specific research at certain</p> <p>15 endpoints. Moving forward the company felt that they</p> <p>16 had already invested a significant amount of resources</p> <p>17 and felt that they had already adequately demonstrated</p> <p>18 what the FDA was asking for, but the FDA was not</p> <p>19 satisfied with what had been provided and wanted</p> <p>20 everything to sort of be redone.</p> <p>21 Q. And, to your understanding, what did</p> <p>22 Ethicon do in response to that?</p> <p>23 A. Again, I wasn't involved at that level</p> <p>24 in the decision-making itself. It's my understanding</p>

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<p style="text-align: right;">Page 130</p> <p>1 that they chose to withdraw the products, the family of</p> <p>2 products on the market.</p> <p>3 Q. Rather than perform the studies that the</p> <p>4 FDA was asking for?</p> <p>5 A. I mean, I don't know that it's a rather</p> <p>6 than. They just decided to withdraw the products.</p> <p>7 Q. And the defendants haven't made you</p> <p>8 privy to any of the internal communications regarding</p> <p>9 this business decision, have they?</p> <p>10 MR. SNELL: Who? Answer to your</p> <p>11 recollection.</p> <p>12 THE WITNESS: To my recollection, I</p> <p>13 don't remember being privy to that information,</p> <p>14 no.</p> <p>15 MR. SCHNIEDERS: Do you have a --</p> <p>16 MR. SNELL: Well, I mean, he has the 522</p> <p>17 orders and the back and forth of what the FDA</p> <p>18 said, if that's what you're talking about. I</p> <p>19 should have objected because your question was</p> <p>20 a little vague. I wasn't quite sure what you</p> <p>21 were talking about exactly.</p> <p>22 MR. SCHNIEDERS: I said internal -- you</p> <p>23 got real time right there, just read it. It</p> <p>24 says and the defendants haven't made you privy</p>	<p style="text-align: right;">Page 132</p> <p>1 extra testing?</p> <p>2 MR. SNELL: Form, foundation.</p> <p>3 THE WITNESS: I have no curiosity in</p> <p>4 that domain. I have plenty of other work to</p> <p>5 occupy my time.</p> <p>6 BY MR. SCHNIEDERS:</p> <p>7 Q. But, as we sit here today, and we've</p> <p>8 established from your expert report you believe that,</p> <p>9 for instance, the Prolift is a safe product when used</p> <p>10 according to its indications, correct?</p> <p>11 A. I think that we have over 3,000 clinical</p> <p>12 trials involving tens of thousands of women with data</p> <p>13 collected out to seven years that more than adequately</p> <p>14 supports the use of Prolift for the treatment of</p> <p>15 prolapse in women as an effective product, correct.</p> <p>16 Q. But you don't know why the defendant</p> <p>17 pulled the product, if that's the case, correct?</p> <p>18 MR. SNELL: Form, foundation, asked and</p> <p>19 answered.</p> <p>20 THE WITNESS: I'm assuming like much in</p> <p>21 life, it was a business decision. They</p> <p>22 balanced potential revenue versus whatever</p> <p>23 investments, and but no.</p> <p>24 BY MR. SCHNIEDERS:</p>
<p style="text-align: right;">Page 131</p> <p>1 to any of the internal communications regarding</p> <p>2 this business decision, have they, and I think</p> <p>3 the answer is no, to your recollection.</p> <p>4 MR. SNELL: I don't know. I haven't</p> <p>5 looked through everything Ostergard has, and</p> <p>6 there's a huge binder, and if it's in his</p> <p>7 stuff, it's been given to him.</p> <p>8 THE WITNESS: But, no, I have not.</p> <p>9 BY MR. SCHNIEDERS:</p> <p>10 Q. Okay.</p> <p>11 A. In my recollection is that I have not.</p> <p>12 I don't recollect, rather. I'm sorry.</p> <p>13 Q. And the most recent things that you</p> <p>14 might have read would have been Ostergard, correct?</p> <p>15 A. I don't recall reading any of that in</p> <p>16 Ostergard, but, no.</p> <p>17 Q. Have you asked the defendant for any of</p> <p>18 those internal communications?</p> <p>19 A. I have not.</p> <p>20 Q. Why not?</p> <p>21 A. I don't consider them to be relevant to</p> <p>22 my generating the expert report.</p> <p>23 Q. You're not curious what their</p> <p>24 decision-making process was in to why they wouldn't do</p>	<p style="text-align: right;">Page 133</p> <p>1 Q. It was a money decision?</p> <p>2 A. I don't know.</p> <p>3 MR. SNELL: Same objection.</p> <p>4 THE WITNESS: I don't know, sir. I'm</p> <p>5 sorry.</p> <p>6 BY MR. SCHNIEDERS:</p> <p>7 Q. We've established in the six to eight</p> <p>8 procedures per week, at least several of them are going</p> <p>9 to involve the products that you are testifying in this</p> <p>10 litigation?</p> <p>11 A. That is correct.</p> <p>12 Q. So take me through when you have a woman</p> <p>13 that comes in with pelvic organ prolapse and you've</p> <p>14 determined that Gynemesh PS would be a suitable</p> <p>15 surgical placement for her, what do you tell her about</p> <p>16 the risks and benefits?</p> <p>17 A. Specifically, the discussion is the</p> <p>18 same. Women with prolapse have a certain set of</p> <p>19 baseline symptoms. Obviously, they have both symptoms.</p> <p>20 They frequently have bladder or bowel dysfunction. The</p> <p>21 majority of them have pre-existing sexual dysfunction.</p> <p>22 We explain to them the intent and the limitations of</p> <p>23 surgery in general in correcting those problems. I try</p> <p>24 to set realistic expectations as far as what is likely</p>

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<p style="text-align: right;">Page 134</p> <p>1 to get better, what may not get better, and then we 2 start to go through their options. 3 As I go through their options, I try to, in a 4 fairly nondirective manner, to guide them to a decision 5 based very much on the information that we're reading 6 in my report. You know, these are the different 7 procedures at our disposal. These are the different 8 approaches. Some of these approaches may include 9 hysterectomy or not hysterectomy. Some may involve 10 simple tissue plication. Some are done abdominally, 11 some are done vaginally, some are done as a combination 12 of both. Some may involve the placement of mesh 13 surrounding the vagina, and we go over what these 14 women's priorities are, what their concerns are, what 15 they hope to accomplish. We look at their ages, their 16 co-morbidities, and I try to help them on an individual 17 level to make a decision that's best for them. 18 Q. And on the topic of mesh and more 19 specifically Gynemesh PS comes up, what do you tell 20 them the risks are of that procedure? 21 A. Again, the conversation is largely, you 22 know, all prolapse surgery come with very similar risks 23 in terms of whether or not it will be successful, 24 whether or not you will develop normal bladder</p>	<p style="text-align: right;">Page 136</p> <p>1 procedure. 2 Rarely do I think the mesh has anything to do 3 with that. You know, I think certainly if you look at 4 the report, counselor, vaginal length tends to be 5 longer when we use the mesh, sex tends to be more 6 comfortable when we use the mesh. The incidence of 7 pain is no higher than it is with the other techniques. 8 The incidence of dyspareunia in most studies is 9 extremely low, you know, certainly 10% is the summary 10 incident that we will talk about. In randomized 11 trials, it's been as low as 3%. 12 Native tissue repairs, in my opinion and in the 13 literature that I've reviewed, often times have 14 dyspareunia rates that are far higher, 15%, 25%. 15 Again, it's a complicated discussion. The majority of 16 these people have some degree of pain with sex prior to 17 surgery. We have to speak about the likelihood that 18 that pain will improve. There are some women that have 19 no pain. We talk about the chance or the rates of de 20 novo dyspareunia. It's not a black-and-white kind of 21 discussion, and it's typically a discussion that takes 22 place over three or four visits. 23 MR. SCHNIEDERS: I will object and move 24 to strike as nonresponsive.</p>
<p style="text-align: right;">Page 135</p> <p>1 emptying, abnormal bladder emptying, could you 2 experience chronic pain, could you experience pain with 3 sexual intercourse. I can't tell you that I -- you 4 know, I don't necessarily distinguish from one to the 5 other in a general sense. 6 Obviously, if we're going to implant mesh, I 7 speak to them about the fact that polypropylene mesh is 8 the most widely used material in our field, that 9 there's experience that goes back decades. That, in 10 general, this is the consensus standard of care 11 material used throughout the world, and obviously we 12 talk to them a little bit about our personal experience 13 in our practice and over my 24, 25 years of clinical 14 practice. 15 Q. So when you're talking to a woman about 16 placement of Gynemesh PS, do you tell her that it's 17 possible that she will have chronic pain following the 18 surgery? 19 A. To be honest with you, we rarely see 20 pain as a consequence of these procedures. I certainly 21 will say that there's always the potential for pain. 22 Again, I don't believe that it's the mesh itself. To 23 be honest with you, most of the pain that we see is 24 certainly more related to the plication parts of the</p>	<p style="text-align: right;">Page 137</p> <p>1 BY MR. SCHNIEDERS: 2 Q. Doctor, when you are talking to a women 3 about placement of Gynemesh PS, do you tell her it's 4 possible that she will have chronic pain following the 5 surgery? 6 MR. SNELL: Objection. I think he's 7 asked and answered that. 8 THE WITNESS: Okay. So the Gynemesh is 9 only one part of the surgical procedure that 10 I'm doing. So we are talking -- I talk to them 11 about the overall risk of the surgical 12 intervention. If we're going to do a 13 hysterectomy and a sacrocolpopexy with mesh and 14 a posterior repair, I'm talking about the 15 overall likelihood of complications. 16 MR. SCHNIEDERS: Mark as Exhibit 10 the 17 IFU for Gynemesh PS. 18 (Document marked for identification as 19 Toggia Deposition Exhibit No. 10.) 20 BY MR. SCHNIEDERS: 21 Q. Doctor, are you familiar with this 22 document? 23 A. I am familiar with the IFU, yes. 24 Q. For the jury's benefit, what does the</p>

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<p>1 IFU tell a doctor?</p> <p>2 A. The IFU stands for information for use.</p> <p>3 It's a document that will explain everything from the</p> <p>4 material you use, how it's sterilized what the intended</p> <p>5 uses are, situations in which it might be used. There</p> <p>6 is a listing of precaution and adverse events that are</p> <p>7 known and some suggestions to the surgeon to keep in</p> <p>8 mind when the surgeon is coming up with a surgical</p> <p>9 plan.</p> <p>10 Q. And this is the 2015 version of this IFU</p> <p>11 because you understand that this IFU is updated</p> <p>12 February of 2015, correct?</p> <p>13 A. That is my understanding, correct.</p> <p>14 Q. Do you make it a habit as a surgeon to</p> <p>15 read the IFUs for all products that you're placing?</p> <p>16 A. I am pretty much an instruction reader</p> <p>17 in general. I even read the instructions to my VCR and</p> <p>18 my phone, although, obviously, I missed the part about</p> <p>19 the voice speaking, but, yes, I am -- I do read, and</p> <p>20 largely, you know, I do teach, so I want to make sure</p> <p>21 that what I say is consistent with the IFU.</p> <p>22 Q. Just excited you still have a VCR.</p> <p>23 A. I know, right.</p> <p>24 Q. If you go to the indications, what are</p>	<p>1 A. I'm aware through my review of these</p> <p>2 materials. I can't tell you at the specific moment</p> <p>3 that it was removed from the market that I was abruptly</p> <p>4 aware of that.</p> <p>5 Q. So there wasn't an Ethicon rep that was</p> <p>6 coming by your office to let you know?</p> <p>7 A. I mean, in general, I'm an expert in</p> <p>8 this area. I possess far more expertise than</p> <p>9 representatives. I can't tell you that I really depend</p> <p>10 upon the sales rep, in general. I know most things way</p> <p>11 before and beyond what any of the sales reps, so I</p> <p>12 cannot tell you that I have -- you know, that that's</p> <p>13 a -- where I depend upon the information from.</p> <p>14 Q. But fair to say that the IFU is a</p> <p>15 document that's intended to give surgeons additional</p> <p>16 information about a product, including safety</p> <p>17 information, correct?</p> <p>18 A. It's a document that provides guidance.</p> <p>19 Q. If you go to the third page under</p> <p>20 adverse reactions, and I can mark the other IFU, if you</p> <p>21 like, Doctor, but if you have a recollection, do you</p> <p>22 recall that -- well, actually, let's just do it this</p> <p>23 way.</p> <p>24 Strike that.</p>
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<p>1 the indications for Gynemesh PS? It's on the second</p> <p>2 page.</p> <p>3 A. With the understanding that as a</p> <p>4 surgeon, I've got the ability to use things as I see,</p> <p>5 you know, fit for what I'm working on. Specifically,</p> <p>6 we use Gynemesh for the correction of pelvic organ</p> <p>7 prolapse. What it says here specifically that it's</p> <p>8 being used as a bridging material for apical, vaginal</p> <p>9 and uterine prolapse. This one here that you've given</p> <p>10 me specifically, in my opinion, is referring to an</p> <p>11 abdominal approach.</p> <p>12 Q. Okay. And was Gynemesh previously</p> <p>13 indicated for only an abdominal approach?</p> <p>14 A. My understanding back in 2002, when</p> <p>15 Gynemesh -- Gynemesh PS received its indication, it was</p> <p>16 not stated in the same language, it was stated in a</p> <p>17 much more general sense that it could be used for</p> <p>18 prolapse, and the implication was either abdominally or</p> <p>19 vaginally.</p> <p>20 Q. And is it your -- do you have the --</p> <p>21 strike that.</p> <p>22 Are you aware that that indication was changed</p> <p>23 at the same time that Prolift was removed from the</p> <p>24 market?</p>	<p>1 (Document marked for identification as</p> <p>2 Toggia Deposition Exhibit No. 11.)</p> <p>3 BY MR. SCHNIEDERS:</p> <p>4 Q. I'm marking as Exhibit 11 the previous</p> <p>5 IFU for Gynemesh PS, although I apologize that it's got</p> <p>6 a lot of other languages in there along with it. But</p> <p>7 the English version should be right out front.</p> <p>8 So, Doctor, if you go to what we've marked now</p> <p>9 as Exhibit 11, that is the version of the IFU for</p> <p>10 Gynemesh PS that was in effect previous to this</p> <p>11 February of 2015.</p> <p>12 Does that look consistent with your</p> <p>13 recollection?</p> <p>14 MR. SNELL: Give me a second to look at</p> <p>15 it. Okay. Go ahead.</p> <p>16 THE WITNESS: Sure. The date on here is</p> <p>17 September 15, 2008. I agree with you that this</p> <p>18 one preceded this one.</p> <p>19 BY MR. SCHNIEDERS:</p> <p>20 Q. If you look at the second page, would</p> <p>21 you look at the indication there for Gynemesh PS as of</p> <p>22 2008?</p> <p>23 A. Yes, I do see that paragraph.</p> <p>24 Q. And that's a different indication than</p>

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<p style="text-align: right;">Page 142</p> <p>1 what is in place in February of 2015, correct?</p> <p>2 MR. SNELL: Foundation.</p> <p>3 THE WITNESS: I would say the</p> <p>4 indications to me seem similar. The wording</p> <p>5 has been changed. In both they mention that</p> <p>6 the material is used for bridging material for</p> <p>7 the treatment of prolapse. One mentions</p> <p>8 vaginal wall. The other one is more inclusive</p> <p>9 of apical, vaginal and uterine. So, I mean,</p> <p>10 the language is slightly different. My opinion</p> <p>11 is the intent is pretty much the same.</p> <p>12 BY MR. SCHNIEDERS:</p> <p>13 Q. But the previous version of the IFU</p> <p>14 didn't infer an abdominal approach, correct?</p> <p>15 A. Correct.</p> <p>16 Q. Whereas the February 2015 IFU does,</p> <p>17 correct?</p> <p>18 A. Correct.</p> <p>19 Q. Okay. Doctor, if you go to the third</p> <p>20 page of both IFUs, you'll find the section that's</p> <p>21 called adverse reactions, and you can see just by</p> <p>22 looking at it at first glance, that the adverse</p> <p>23 reactions section in 2015 is much longer than it was in</p> <p>24 the previous version, correct?</p>	<p style="text-align: right;">Page 144</p> <p>1 the next page as well, so ten more, correct?</p> <p>2 A. Yes.</p> <p>3 Q. Okay.</p> <p>4 A. Well, and then there are other adverse</p> <p>5 reactions, but I'm with you, counsel. I'm following</p> <p>6 along with you.</p> <p>7 Q. Okay. So that second bullet point there</p> <p>8 that starts with "as with any implants," could you read</p> <p>9 that, Doctor.</p> <p>10 A. As with any implant, a foreign body</p> <p>11 response may occur. This response could result in</p> <p>12 extrusion, exposure -- excuse me -- erosion, exposure,</p> <p>13 fistula formation and/or inflammation.</p> <p>14 Q. And the third bullet point there that</p> <p>15 begins with "potential adverse reactions," could you</p> <p>16 read that?</p> <p>17 A. Potential adverse reactions are those</p> <p>18 typically associated with pelvic organ prolapse repair</p> <p>19 procedures, including pelvic pain, pain with</p> <p>20 intercourse, which in some patients may not resolve.</p> <p>21 Q. If you go to the bullet point that</p> <p>22 begins with "excessive contraction," could you read</p> <p>23 that, Doctor.</p> <p>24 A. "Excessive contraction or shrinkage of</p>
<p style="text-align: right;">Page 143</p> <p>1 A. Yes.</p> <p>2 Q. And under -- in the previous version it</p> <p>3 states potential adverse reactions are those typically</p> <p>4 associated with surgically implantable materials,</p> <p>5 including infection, potentiation, inflammation,</p> <p>6 adhesion formation, fistula formation, erosion,</p> <p>7 extrusion and scarring that results in implant</p> <p>8 contraction.</p> <p>9 Did I read that correctly?</p> <p>10 A. Yes, you did.</p> <p>11 Q. And that's the only thing that's listed</p> <p>12 under adverse reactions in the previous IFU, correct?</p> <p>13 A. Yes.</p> <p>14 Q. If we go to the more recent IFU, I</p> <p>15 believe that that bullet point essentially that I just</p> <p>16 read with a few additional terms appears as the first</p> <p>17 bullet point in adverse reactions.</p> <p>18 Does that look like a fair reading?</p> <p>19 A. I agree.</p> <p>20 Q. And then there's several -- there's</p> <p>21 eight more bullet points that follow in adverse</p> <p>22 reactions, correct?</p> <p>23 A. Yes.</p> <p>24 Q. And I missed two. There's two more on</p>	<p style="text-align: right;">Page 145</p> <p>1 the tissue surrounding the mesh, vaginal scarring,</p> <p>2 tightening and/or shortening may occur."</p> <p>3 Q. And what would happen if there was</p> <p>4 excessive contraction or shrinkage of the tissue</p> <p>5 surrounding the mesh?</p> <p>6 A. I guess it would vary, depending upon</p> <p>7 where specifically we were talking about that.</p> <p>8 Q. As the expert here, Doctor, tell me what</p> <p>9 are the different alternatives.</p> <p>10 A. As the expert I can tell you I've never</p> <p>11 observed shortening or shrinking or scarring, but,</p> <p>12 again, I'm speaking to, you know, in the anterior</p> <p>13 compartment, there could be some influence on bladder</p> <p>14 function. At the apical end of things, I would think</p> <p>15 that it could affect sexual intercourse. In the</p> <p>16 posterior compartment, there could be events there,</p> <p>17 although, again, I point out in my report, I evaluated</p> <p>18 this extensively, and there's no evidence from the</p> <p>19 literature that these types of events are occurring</p> <p>20 with any greater frequency with these products as</p> <p>21 compared to other types of repairs, and that is</p> <p>22 inferred in the paragraph I believe that you read</p> <p>23 yourself, that these are risks typically associated</p> <p>24 with pelvic organ prolapse repair.</p>

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<p>1 Q. Actually, that's the first paragraph.</p> <p>2 A. Sorry. Third bullet point, "Potential</p> <p>3 adverse reactions are those typically associated with</p> <p>4 pelvic organ prolapse repair procedures."</p> <p>5 Q. And obviously excessive contraction or</p> <p>6 shrinkage of the tissue surrounding the mesh, vaginal</p> <p>7 scarring, tightening and/or shortening is not something</p> <p>8 that is caused by pelvic organ prolapse, correct?</p> <p>9 A. Pelvic organ prolapse or pelvic organ</p> <p>10 prolapse repair procedures?</p> <p>11 Q. Fair enough. The repair procedure.</p> <p>12 A. It is, and, again, if you read through</p> <p>13 my report, these are common adverse events that are</p> <p>14 associated. That's why it says that. It says</p> <p>15 potential reactions and it says typical, not unusual,</p> <p>16 typically associated with pelvic organ prolapse repair</p> <p>17 procedures. And, again, I have cited several very</p> <p>18 reputable sources analyzing over 100 studies involving</p> <p>19 10, 11,000 patients suggesting low incidence of these</p> <p>20 things and incidences that are not any different than</p> <p>21 what is typically associated with pelvic organ prolapse</p> <p>22 repair that does not involve mesh.</p> <p>23 Q. Regardless of whether it's caused by</p> <p>24 pelvic organ prolapse repair or by the mesh, you've</p>	<p>1 materials I provided for you, and these were suture</p> <p>2 based repairs, nerve pain was observed in one arm,</p> <p>3 6.9%, in the second arm 12.4%.</p> <p>4 Q. Okay. In your risk-benefit discussion</p> <p>5 with a patient who is potentially going to have a</p> <p>6 Gynemesh PS placed, do you tell her that excessive</p> <p>7 contraction or shrinkage of the tissue surrounding the</p> <p>8 mesh, vaginal scarring, tightening and/or shortening</p> <p>9 may occur?</p> <p>10 A. Again, we don't do these procedures in</p> <p>11 isolation, so I speak to them about the total</p> <p>12 procedure. In general, that's not been our experience</p> <p>13 to see that, but I do explain to them that sometimes</p> <p>14 surgery can result in pain, either pain during sex or</p> <p>15 even pain not related to sex. And, obviously, they</p> <p>16 have an incision in the vagina. It's -- the incision</p> <p>17 is obviously going to be tender initially. That</p> <p>18 tenderness usually resolves over time; however, there</p> <p>19 are instances in which the pain will persist. I don't</p> <p>20 specifically say it's the product that causes those</p> <p>21 procedure because based upon the records -- excuse me,</p> <p>22 the literature that I have reviewed and my own personal</p> <p>23 experience in 25 years, that has not been what we have</p> <p>24 observed or is what's been reported.</p>
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<p>1 never seen it either way, right?</p> <p>2 A. That's not what I've said, sir. I said</p> <p>3 that, in my experience, as I stated in my report, I've</p> <p>4 never seen the mesh cause shrinkage or scarring above</p> <p>5 or beyond what we would typically see.</p> <p>6 Q. Do you see the second to last bullet</p> <p>7 point that says "neuromuscular problems, including</p> <p>8 acute and/or chronic pain in the groin, thigh, leg,</p> <p>9 pelvic and/or abdominal area may occur"?</p> <p>10 A. I do see that.</p> <p>11 Q. Do you agree with that statement?</p> <p>12 A. I agree, yes, that with pelvic organ</p> <p>13 prolapse repair procedures that we do that those</p> <p>14 problems can occur. They can occur with suture based</p> <p>15 repairs. They can occur with mesh based repairs. If I</p> <p>16 could refer you to the study, and I'm sorry, some of</p> <p>17 these names I have trouble pronouncing, he did</p> <p>18 sacrospinous ligament suspension, Qataweh, okay, he</p> <p>19 points out, for example, temporary sciatic neuralgia,</p> <p>20 this is on Page 15 of my report, pointed out that about</p> <p>21 I believe it was 11% of patients in either group</p> <p>22 experienced sciatic neuralgia.</p> <p>23 Actually, Barber et al. in what's the OPTIMAL</p> <p>24 trial, and the OPTIMAL trial is included in the</p>	<p>1 Q. Do you tell that woman that potentially</p> <p>2 is going to have Gynemesh placed that neuromuscular</p> <p>3 problems, including acute and/or chronic pain in the</p> <p>4 groin, thigh, leg pelvic and/or abdominal area may</p> <p>5 occur.</p> <p>6 A. I think that's what we just address, in</p> <p>7 general I tell them that is part of the risks of</p> <p>8 surgery in general for pelvic organ prolapse, that they</p> <p>9 are uncommon problems, and, again, if it's a patient</p> <p>10 with fibromyalgia, they probably have a little bit</p> <p>11 higher risk because they're already sort of predisposed</p> <p>12 to that. Again, it may vary based upon age. So it's</p> <p>13 really a general discussion that is sort of tuned for</p> <p>14 that individual, but, overall, I am covering the</p> <p>15 general topics as listed in -- that we've just been</p> <p>16 discussing from the IFU.</p> <p>17 Q. But your discussion with women that are</p> <p>18 undergoing surgery to correct pelvic organ prolapse is</p> <p>19 the same, regardless of whether you're placing a mesh</p> <p>20 or you're doing any other surgery, correct?</p> <p>21 A. Yes, because the risks are the same.</p> <p>22 Incidence of dyspareunia, pain, defecatory dysfunction,</p> <p>23 voiding dysfunction, incontinence, in general is not</p> <p>24 different percentage-wise between the procedures, and</p>

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<p>1 that is sort of the sum and basis of the report that</p> <p>2 I've generated for this purpose.</p> <p>3 Q. Do you tell a woman that potentially is</p> <p>4 to receive a Gynemesh PS product that at some point</p> <p>5 another surgeon or you may have to go in there and</p> <p>6 remove the mesh?</p> <p>7 A. In general, I inform the woman that the</p> <p>8 mesh is permanent, that the good news is that,</p> <p>9 typically, if we get a satisfactory result, that result</p> <p>10 is long lasting. I explain to them that typically the</p> <p>11 literature has supported that repairs done with mesh</p> <p>12 are typically superior to the results without mesh, and</p> <p>13 that certainly has matched our personal experience in</p> <p>14 this field in the last 25 years, but, yes, if they were</p> <p>15 to develop pain that there may be a risk of</p> <p>16 re-intervention. Typically, that risk of</p> <p>17 re-intervention is low in our practice. It's probably</p> <p>18 5%.</p> <p>19 The literature would suggest that the risk of</p> <p>20 re-intervention is in the low teens, again, depending</p> <p>21 risk factors. What's the patient's age, is she a</p> <p>22 smoker, is she obese. So sometimes I do fine-tune that</p> <p>23 and say I would consider you to be somebody at a little</p> <p>24 bit higher risk than what I'm explaining to you right</p>	<p>1 literature, they occur at least with equal frequency.</p> <p>2 In our hands, they occurred three times higher with</p> <p>3 suture based repairs.</p> <p>4 Q. Did you ever approach Ethicon and ask</p> <p>5 that Gynemesh's mesh be less rigid?</p> <p>6 A. I don't know. I'm concerned because you</p> <p>7 seem to be reading from something while you're asking</p> <p>8 me that question, but I honestly don't know. I'm sure</p> <p>9 I offered them opinions, again, in a theoretical sense</p> <p>10 whether it was Prolift+M, whether it was Prolift,</p> <p>11 whether it was Gynemesh, there were subtle variations,</p> <p>12 there were other products from other companies, I may</p> <p>13 have had ideas about what I thought.</p> <p>14 I mean, my recollection is that I said to them,</p> <p>15 look, at least in my observation, I find that, you</p> <p>16 know, Prolift+M is a more rigid material. At the time</p> <p>17 of implantation, that may be beneficial, it's a little</p> <p>18 easier to work with if it's rigid; however, it could,</p> <p>19 in fact, maybe be associated with more wound</p> <p>20 complications, and I would let them know that just so</p> <p>21 they can just include that in the information that</p> <p>22 they're receiving.</p> <p>23 You know, again, I tended to be an early</p> <p>24 adopter of these procedures, and I felt a</p>
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<p>1 now or somebody that I believe are a little bit lower</p> <p>2 risk, but, again, it's always part of that general</p> <p>3 discussion about the surgery in general because we</p> <p>4 rarely go in and just sort of do one thing and nothing</p> <p>5 else.</p> <p>6 Q. But it's fair to say that if mesh is</p> <p>7 never placed, that you don't have to go in and remove</p> <p>8 mesh if there's a complication, correct?</p> <p>9 A. If mesh is not placed, then you don't</p> <p>10 have to go in to remove mesh. If suture is placed, you</p> <p>11 may have to go in to remove sutures, and, again, in our</p> <p>12 experience, those occur with equal likelihood.</p> <p>13 Q. With sutures there's equal likelihood</p> <p>14 that another intervention would be necessary?</p> <p>15 A. Correct. In fact, I published a paper</p> <p>16 in which the likelihood re-intervention to remove</p> <p>17 sutures exceeded 30%, and that is certainly -- that is</p> <p>18 probably three times the incidence of us having to go</p> <p>19 back to deal with mesh-related wound -- I'm just going</p> <p>20 to classify these are all types of wound complications.</p> <p>21 So whether the wound opens up, whether there's a suture</p> <p>22 that's exposed, whether the wound opens up and mesh is</p> <p>23 exposed, that's a wound complication.</p> <p>24 In our practice and supported by the</p>	<p>1 responsibility as an early adopter to provide early</p> <p>2 feedback.</p> <p>3 Q. What is your understanding of what a KOL</p> <p>4 is?</p> <p>5 A. A KOL is a term that means key opinion</p> <p>6 leaders, and it's a term used by industry to identify</p> <p>7 people that they considered to be key opinion leaders.</p> <p>8 What they specifically mean by that and what I might</p> <p>9 think about that may not be the same thing.</p> <p>10 Q. Would you have considered yourself to be</p> <p>11 a KOL for industry?</p> <p>12 A. I mean, I think they might consider me</p> <p>13 to be a KOL. You know, I mean, certainly, at this</p> <p>14 point in time, I've been doing this for a long time, I</p> <p>15 do a high clinical volume, I'm a relatively</p> <p>16 straightforward and approachable person, and I'm pretty</p> <p>17 liberal with my opinions, but I would say -- sorry to</p> <p>18 give you a long-winded answer, I know that</p> <p>19 organizations have considered me to be a key opinion</p> <p>20 leader in this area.</p> <p>21 Q. What is -- in medicine, what's a</p> <p>22 conflict of interest?</p> <p>23 MR. SNELL: Form, overbroad.</p> <p>24 THE WITNESS: Exactly. You know, I</p>

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<p>1 mean, there are very many different forms of</p> <p>2 conflict of interest. I mean, you know, I'd</p> <p>3 have to get -- have a specific situation.</p> <p>4 BY MR. SCHNIEDERS:</p> <p>5 Q. Well, when drafting an article, is it</p> <p>6 part of the canon that physicians will disclose</p> <p>7 potential conflicts they might have that could</p> <p>8 potentially affect their opinion?</p> <p>9 MR. SNELL: Form, vague, also undefined</p> <p>10 as to scope and time.</p> <p>11 THE WITNESS: You know, I think there's</p> <p>12 a fine line between bias and conflict of</p> <p>13 interest, however, you know. For example, in</p> <p>14 the TVT Secur trial, I revealed to the</p> <p>15 publishing journal and the people reviewing the</p> <p>16 manuscript that, you know, yes, I have taught</p> <p>17 this procedure and I have been compensated for</p> <p>18 that time.</p> <p>19 I'll tell you, quite honestly, I don't</p> <p>20 think the results of that trial was of any</p> <p>21 benefit to the company, you know. The company</p> <p>22 did not pay for that trial directly. It</p> <p>23 involved their products, so my involvement was</p> <p>24 based on my experience. My involvement was not</p>	<p>1 A. You know, it's just one of a host of</p> <p>2 variables. Everybody clearly has a bias, you know, or</p> <p>3 a prejudice, you know, many of which might be based</p> <p>4 upon personal experience. So, you know, even if</p> <p>5 there's no industry related conflict, you know, there's</p> <p>6 always bias involved, and it's just one thing to keep</p> <p>7 in mind and it's a very -- you have to balance, you</p> <p>8 know, that with everything else that you're reading.</p> <p>9 Q. And is that something that you as a</p> <p>10 reviewer of literature do when you're reviewing</p> <p>11 studies, for instance, in this case?</p> <p>12 A. We look at their disclosures, you know.</p> <p>13 We looked at funding for the study direct. We look at</p> <p>14 what the authors would reveal as potential conflicts.</p> <p>15 I can't tell you that that is -- that commonly changes</p> <p>16 the overall value of the report or what's being said.</p> <p>17 The results typically speak for themselves. There are</p> <p>18 a number of internal controls.</p> <p>19 So, for example, when you randomize somebody to</p> <p>20 one intervention or the other, you're looking to</p> <p>21 minimize bias. When you do a randomized trial that</p> <p>22 might involve over 50 surgeons across five different</p> <p>23 countries, as had been done, for example, with Prolift,</p> <p>24 you will also minimize those biases as well. When</p>
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<p>1 based upon the fact that I had a relationship</p> <p>2 with the company, but I understand that some</p> <p>3 people might view that as a negative, so I did</p> <p>4 disclose that.</p> <p>5 BY MR. SCHNIEDERS:</p> <p>6 Q. Well, what's the purpose of disclosing</p> <p>7 conflicts in literature?</p> <p>8 MR. SNELL: Same objection.</p> <p>9 THE WITNESS: You know, I think when you</p> <p>10 read something, you're trying to understand</p> <p>11 where that person is coming from and whether or</p> <p>12 not they may be otherwise motivated. You know,</p> <p>13 if I own stock in a company, I could run around</p> <p>14 and say -- you know, if I own stock in</p> <p>15 Volkswagen and I drove a Volkswagen, I might</p> <p>16 tell Bert and yourself and anybody else what a</p> <p>17 great car, I've never driven a better car, and</p> <p>18 I own stock in this company because I've got a</p> <p>19 conflict, in a sense. So that's how I would</p> <p>20 view a conflict. I might be otherwise</p> <p>21 motivated in revealing that information.</p> <p>22 BY MR. SCHNIEDERS:</p> <p>23 Q. As a physician, when you're reading</p> <p>24 literature how do you factor in potential conflicts?</p>	<p>1 things are blinded to the patient, you're trying to</p> <p>2 minimize the bias. If the patient knew that they were</p> <p>3 having the same procedure that maybe their sister had</p> <p>4 and their sister had a great result, for example.</p> <p>5 Obviously it's a little harder to blind a</p> <p>6 surgeon. You can't blind them to do the actual</p> <p>7 procedure, I don't think that would be safe, but</p> <p>8 sometimes the person who is doing the evaluation of the</p> <p>9 result might be blinded to what the surgeon did. That</p> <p>10 was the case, for example, I believe with the TVT Secur</p> <p>11 trial, it was sort of single blinded in that regard.</p> <p>12 Q. Is it significant to you when you review</p> <p>13 literature how much money one of the authors might have</p> <p>14 made from a company that that study benefits?</p> <p>15 A. Typically, no.</p> <p>16 Q. Is there a threshold where it does</p> <p>17 become important, for instance, if they make \$500,000?</p> <p>18 A. I'm not aware -- I don't have a</p> <p>19 threshold, no.</p> <p>20 Q. So not a million dollars?</p> <p>21 A. I don't have a threshold.</p> <p>22 Q. \$10 million?</p> <p>23 A. I don't know how I can say I don't have</p> <p>24 a threshold any differently. You know, again, from</p>

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<p>1 where I sit, as you can tell from my report, I'm more 2 interested in the -- what we call sort of the summary 3 or the pooled analysis of data. I'm not going to hold 4 any single study as being the Holy Grail. I'm looking 5 for consistencies between studies. I'm factoring in 6 thing like biological plausibility to what's being 7 offered. I'm looking very specifically at levels of 8 evidence, you know, reproducibility of the results. 9 Those are far more important to me than who was paid 10 what for what and why.</p> <p>11 Q. Who other than authors of a study should 12 hold editorial power over the study?</p> <p>13 MR. SNELL: Form.</p> <p>14 THE WITNESS: You know, again, all 15 studies are different. You know, some 16 studies -- you know, if somebody is paying for 17 a study to be performed, and, again, that's an 18 arrangement made between the investigator and 19 the source of the research, you know, for 20 example, the NIH if they're going to sponsor a 21 study, they oftentimes will insist that that 22 study be available at no cost in a public forum 23 to anybody who might want.</p> <p>24 Certainly, in some of these studies that</p>	<p>1 MR. SNELL: Objection, vague, lacks 2 foundation, incomplete hypothetical.</p> <p>3 THE WITNESS: I think if -- I think that 4 typically that is an agreement and a decision 5 that is made before the study actually begins 6 and, therefore, is kind of sort of removed from 7 the actual results of the study, so it varies 8 widely. You know, as an investigator you have 9 to decide your level of comfort of that 10 involvement.</p> <p>11 You know, you appear to be maybe too 12 young to have children in college, but it's the 13 same argument, if I'm paying for my son to go 14 to college, do I deserve to know, you know, his 15 shenanigans, his grades, potential issues, you 16 know. Again, there are agreements between you 17 and your child, between you and the school, 18 same thing in here. But those are usually 19 clearly defined at the time that there's an 20 agreement to fund the study and it varies.</p> <p>21 BY MR. SCHNIEDERS:</p> <p>22 Q. In your study that was funded by 23 Ethicon, did they have editorial control?</p> <p>24 A. My study was not funded by Ethicon.</p>
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<p>1 were directly funded by the company, the 2 company wanted to have access to those results. 3 I don't know that it is common for there to be 4 any undue influence, but, again, that sort 5 of -- you know, you would think that once a 6 study was published, it's sort of passed 7 certain bars of professionalism to get to that 8 point.</p> <p>9 BY MR. SCHNIEDERS:</p> <p>10 Q. Just so I'm clear because you just said 11 after published, I'm talking about before it's 12 published when it's still a draft manuscript?</p> <p>13 A. Sure. I'm sorry. What I was saying if 14 a study becomes published, you would assume this would 15 have been vetted. It varies, it varies widely, you 16 know, in our experience, as far as how much influence. 17 Sometimes it's simply they want to be aware of the 18 data. You know, sometimes they may want to contribute 19 information. I'm not sure exactly what you're 20 implying.</p> <p>21 Q. I'm just asking is it appropriate for a 22 pharmaceutical or a device company to have a draft copy 23 of a study and add or subtract words from it prior to 24 it being published?</p>	<p>1 Q. It wasn't?</p> <p>2 A. Not directly, no.</p> <p>3 Q. What do you mean "not directly"? That 4 sounds like a qualifier.</p> <p>5 A. My study was not -- again, I was not the 6 study designer, but the study was funded by -- the 7 funding is listed on the actual study, I believe it was 8 the foundation, and I'm sorry if I'm forgetting the 9 exact terms, the foundation of women's health. I did 10 not receive any compensation, and I don't -- it was 11 founded by the foundation, and it was a randomized 12 study between seven sites. So I would violently object 13 to you telling me that that study was funded by Ethicon 14 because it was not.</p> <p>15 Q. And not sure if I'm clear, are you 16 saying you didn't get compensated at all for that 17 study, or you didn't get compensated by Ethicon?</p> <p>18 A. I was not compensated by Ethicon for 19 that study.</p> <p>20 Q. But the foundation, they compensated 21 you, right?</p> <p>22 A. The -- excuse me, the study compensated 23 my practice for the data collection and the clinical 24 nurse coordinator and stuff like that.</p>

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<p>1 Q. Did you get paid anything yourself?</p> <p>2 A. I mean, in my employment all monies go</p> <p>3 into a pool. We subtract expenses from revenue. The</p> <p>4 money doesn't come to me directly labeled or traceable</p> <p>5 from any one site.</p> <p>6 Q. So, clearly, if Ethicon didn't fund your</p> <p>7 study, it would be inappropriate for them to have a</p> <p>8 draft copy and make edits on that, right?</p> <p>9 A. Those are two completely separate</p> <p>10 issues.</p> <p>11 Q. How so?</p> <p>12 MR. SNELL: Objection, asked and</p> <p>13 answered.</p> <p>14 THE WITNESS: Again, I was not part of</p> <p>15 the -- that discussion. I did not discuss the</p> <p>16 study with Ethicon. I don't -- was not part of</p> <p>17 that discussion. My understanding is that they</p> <p>18 saw a copy of the results. I do not believe</p> <p>19 that they had any influence. I will tell you</p> <p>20 that that particular study won two first prizes</p> <p>21 as best surgical paper of the year, both one</p> <p>22 nationally, one internationally. That is not</p> <p>23 something that occurs with an industry -- you</p> <p>24 know, an industry sponsored study.</p>	<p>1 Q. So a moment ago when we were talking</p> <p>2 about KOLs, we discussed the fact that that means key</p> <p>3 opinion leader within the industry, correct?</p> <p>4 A. That's my assumption. I can't tell you</p> <p>5 that anyone has ever -- I've kind of figured that out</p> <p>6 myself. Obviously, it doesn't stand for Knights of</p> <p>7 Columbus, but I'm assuming that that's what that means.</p> <p>8 I have no objection if you tell me that that's what</p> <p>9 that means.</p> <p>10 Q. That's my understanding as well.</p> <p>11 If you see on the front page of this, this is</p> <p>12 from February of 2008, you see that?</p> <p>13 A. And this is coming specifically from</p> <p>14 where?</p> <p>15 Q. This is from Ethicon.</p> <p>16 A. But where specifically within Ethicon?</p> <p>17 This is marketing, this is R&D, this is --</p> <p>18 Q. We would have to get the Bates number</p> <p>19 and tell you whose file it was in, but it's from one of</p> <p>20 their internal files.</p> <p>21 A. Sure.</p> <p>22 Q. So if you go to the third page --</p> <p>23 probably marketing, typically.</p> <p>24 A. I would agree with that. I'm sorry that</p>
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<p>1 BY MR. SCHNIEDERS:</p> <p>2 Q. So that was not an industry sponsored</p> <p>3 study, correct?</p> <p>4 A. Again, I was not -- I did not design the</p> <p>5 study. I am not employed by the foundation that I</p> <p>6 mentioned, so that was not directly funded by Ethicon.</p> <p>7 The foundation collects money from various sources,</p> <p>8 including people like myself that would make a</p> <p>9 contribution. The pooled resources of the foundation</p> <p>10 funded studies. The studies were designed by the</p> <p>11 investigators. The company had no influence on the</p> <p>12 study design. The company had no influence on the</p> <p>13 study results. The company had no influence on the</p> <p>14 writing of the manuscript and they certainly had no</p> <p>15 influence in the presentation or the submission of the</p> <p>16 data. I hope I've clarified that for you because you</p> <p>17 seem to be a little misinformed in that regard.</p> <p>18 (Document marked for identification as</p> <p>19 Togliia Deposition Exhibit No. 12.)</p> <p>20 BY MR. SCHNIEDERS:</p> <p>21 Q. Doctor, I'm showing you what I'm marking</p> <p>22 as Exhibit 12, which is a PowerPoint that came from</p> <p>23 Ethicon and it's entitled "KOL Strategy."</p> <p>24 A. Uh-huh.</p>	<p>1 I led you to that statement.</p> <p>2 Q. Typically, KOLs work with marketing,</p> <p>3 right?</p> <p>4 A. I mean, I was a KOL that worked -- like,</p> <p>5 my involvement, say, with Astellas, which is more</p> <p>6 Astellas global international, my involvement is not</p> <p>7 marketing. It's more R&D, and, you know -- and as</p> <p>8 we've been discussing, much of my relationship and</p> <p>9 interest with Ethicon has been R&D.</p> <p>10 Q. So if we got to this third page that</p> <p>11 says "KOL Categorization," there's a circle with</p> <p>12 several other circles surrounding it?</p> <p>13 A. Yes.</p> <p>14 Q. It starts off it's got the KOL here in</p> <p>15 the middle in the blue circle, and then it's got all</p> <p>16 these different categories, it appears, that whoever</p> <p>17 put this PowerPoint together feels fall within that KOL</p> <p>18 categorization.</p> <p>19 You see that?</p> <p>20 A. Yes.</p> <p>21 Q. And there's things like society or</p> <p>22 influencer, expert user, advocacy/PR, faculty. Are</p> <p>23 those all things that you've seen in other KOLs that</p> <p>24 were with Ethicon as well as you?</p>

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<p style="text-align: right;">Page 166</p> <p>1 MR. SNELL: Foundation.</p> <p>2 THE WITNESS: You know, I got to be</p> <p>3 honest with you, I was not someone that was,</p> <p>4 you know, involved at all levels. I did my</p> <p>5 little piece and stuck to my little piece. To</p> <p>6 me, I look at this, and I'm like, what is a</p> <p>7 KOL? Well, a KOL could be any of these things,</p> <p>8 or all of these things would contribute to a</p> <p>9 KOL. You know, some of these people could be</p> <p>10 physicians, advocacy, could be some of these</p> <p>11 advocacy groups that are out there, the</p> <p>12 incontinence -- National Incontinence Society.</p> <p>13 BY MR. SCHNIEDERS:</p> <p>14 Q. Do you consider AUGS to be an advocacy</p> <p>15 group?</p> <p>16 A. AUGS is an advocacy group, yes.</p> <p>17 Q. If you go to next page, there is a title</p> <p>18 that says "Objective," and there it says, "Engage KOLs</p> <p>19 across the spectrum of functional expertise to partner</p> <p>20 with EWH&U in supporting organizational objectives."</p> <p>21 Did I read that correctly?</p> <p>22 A. You did.</p> <p>23 Q. And EWH&U stands for Ethicon, correct,</p> <p>24 women's health?</p>	<p style="text-align: right;">Page 168</p> <p>1 A. Sure.</p> <p>2 Q. The top one is "Incontinence/Pelvic</p> <p>3 Floor Specialist (UroGyn, GYN)," and of these groups,</p> <p>4 and you can look at it, by all means, but that's</p> <p>5 probably the group that you would identify most</p> <p>6 specifically with, right?</p> <p>7 A. Yes.</p> <p>8 Q. If you go to the next page, it starts</p> <p>9 off with -- it's got a title, it says "Incontinence</p> <p>10 (UroGyn, Gyn)," and then it's got different categories,</p> <p>11 as you can see, in the top. It's got "Prof Ed</p> <p>12 Faculty," which is professional education, right?</p> <p>13 A. Yes.</p> <p>14 Q. And under that it says "National TVT</p> <p>15 Preceptor," and you're at one point a national TVT</p> <p>16 preceptor, weren't you?</p> <p>17 A. Yes, I do believe that I was categorized</p> <p>18 as a national preceptor.</p> <p>19 Q. And there's a category called</p> <p>20 "Published," and under that it says "Published in peer</p> <p>21 reviewed journals." Is that read correctly there?</p> <p>22 A. I'm sorry. I was looking at a different</p> <p>23 page, and I apologize for not paying attention.</p> <p>24 Q. So right next to Prof Ed, there's a</p>
<p style="text-align: right;">Page 167</p> <p>1 A. It stands specifically for Ethicon</p> <p>2 women's health and urology.</p> <p>3 Q. So the group putting this together at</p> <p>4 Ethicon feels that KOLs can be brought in in order to</p> <p>5 support organizational objectives, correct?</p> <p>6 MR. SNELL: Calls for speculation.</p> <p>7 THE WITNESS: Again, you know, my</p> <p>8 role -- and, again, my role as a KOL person of</p> <p>9 influence was infinitesimal. I was not as --</p> <p>10 as they would say, I was not in the starting</p> <p>11 lineup. You know, I take it for what it reads,</p> <p>12 that the objective of this project was to</p> <p>13 engage KOLs across the spectrum, meaning that</p> <p>14 we're not just going to focus on surgeons, you</p> <p>15 know, we're just not going to focus on</p> <p>16 inventors. We're looking for a broad range of</p> <p>17 individuals that might be able to help us.</p> <p>18 BY MR. SCHNIEDERS:</p> <p>19 Q. If you keep going, skip the next page,</p> <p>20 next two pages actually and there should be something</p> <p>21 that says "Categories" at the top. There you go.</p> <p>22 A. Yes.</p> <p>23 Q. And it's got several different</p> <p>24 specialties, for lack of a better term.</p>	<p style="text-align: right;">Page 169</p> <p>1 category called "Published."</p> <p>2 A. Yes.</p> <p>3 Q. And under that it says -- under where it</p> <p>4 says "Description/Criteria," it says "Published in peer</p> <p>5 reviewed journals." Did I read that right?</p> <p>6 A. Yes.</p> <p>7 Q. And then if you go all the way, there's</p> <p>8 "Academic" and then there's "Inventor."</p> <p>9 A. Yes.</p> <p>10 Q. And there's "Emerging," and then there's</p> <p>11 "Expert User."</p> <p>12 A. Okay.</p> <p>13 Q. And "Description/Criteria" is "High</p> <p>14 utilization of product (EWH&U and Competitive)."</p> <p>15 Did I read that correctly?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And what does that mean to you as</p> <p>18 far as high utilization of product?</p> <p>19 A. My interpretation is given that this was</p> <p>20 a marketplace that had 49 slings, my interpretation is</p> <p>21 that if 99% of what you did in this sphere was with our</p> <p>22 product, as opposed to I dabbled with everybody's</p> <p>23 product, I would interpret that to mean, you know, that</p> <p>24 that's where high utilization.</p>

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<p>1 Q. And then there's "Advocacy/PR/Policy"</p> <p>2 and the criteria there is "Practice in top 25 media</p> <p>3 market, academic/society affiliation," and last one is</p> <p>4 "Society Leadership or Influencer, leadership role in</p> <p>5 AUA, AUGS SUFU" --</p> <p>6 A. Sure.</p> <p>7 Q. "AAGL, ACOG, General Influencer."</p> <p>8 A. Uh-huh.</p> <p>9 Q. If you go to the next page, then it puts</p> <p>10 some names here with the group. I'm sure you're</p> <p>11 shocked by that.</p> <p>12 A. I have no vested interest and could care</p> <p>13 less. This is their opinion. It means nothing to me.</p> <p>14 I could care less where -- I'm just laughing as far as,</p> <p>15 you know, they have me listed as an inventor, you know.</p> <p>16 Q. They do?</p> <p>17 A. Yeah, see that.</p> <p>18 Q. They have you listed under inventor</p> <p>19 actively engaged in the creation of new products?</p> <p>20 A. Right. How come I'm not in the top ten?</p> <p>21 Q. And then -- well, you are in the top ten</p> <p>22 on several of these.</p> <p>23 A. No, I'm not. Not on this one I'm not.</p> <p>24 This is TVT.</p>	<p>1 someone that you are a colleague of here in the area,</p> <p>2 right?</p> <p>3 A. Yes.</p> <p>4 Q. And then I believe that in that same</p> <p>5 column there, Mickey Karram was an author along with</p> <p>6 you in your study?</p> <p>7 A. Correct, right.</p> <p>8 Q. Under academic I think Dr. Iglesia was</p> <p>9 an author with you as well?</p> <p>10 A. Yes.</p> <p>11 Q. Sokol is that someone that you're</p> <p>12 familiar with?</p> <p>13 A. Well, that's an interesting thing. The</p> <p>14 Sokols are twins, and they are both urogynecologists,</p> <p>15 and this does not distinguish which Sokol we're talking</p> <p>16 about.</p> <p>17 Q. Both of them happen to be defense</p> <p>18 experts in this litigation, so it could be either one</p> <p>19 of them.</p> <p>20 And then if you go across --</p> <p>21 MR. SNELL: Who for?</p> <p>22 MR. SCHNIEDERS: I don't know the answer</p> <p>23 to that.</p> <p>24 MR. SNELL: I didn't know that. That's</p>
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<p>1 Q. Under "Expert User, High utilization of</p> <p>2 product," you're actually in bold there, if you see</p> <p>3 that down at the bottom?</p> <p>4 A. I have no idea what that means. I'm</p> <p>5 actually on that list twice.</p> <p>6 Q. You are, you are.</p> <p>7 A. Yes, I don't know. I mean, again, I</p> <p>8 don't know how to interpret this, in all fairness.</p> <p>9 Competitive in my mind is, you know, maybe Boston</p> <p>10 Scientific would be interested in this person, so this</p> <p>11 is somebody that, you know, other people might be of</p> <p>12 interest. That's how I would look at competitive.</p> <p>13 High utilization, I mean, you know my history</p> <p>14 with the company, I've used their products extensively,</p> <p>15 more so than any other things. So to me that speaks to</p> <p>16 the fact that I was an early adopter, and I've remained</p> <p>17 engaged throughout that period of time. That's how I</p> <p>18 look at it.</p> <p>19 Q. And if you look at this across the way,</p> <p>20 then you'll see that there's probably some names that</p> <p>21 are very familiar to you as well?</p> <p>22 A. I will tell you almost everybody on this</p> <p>23 list is familiar to me.</p> <p>24 Q. And specifically Vincent Lucente who is</p>	<p>1 news to me.</p> <p>2 THE WITNESS: I'm sorry. Are you</p> <p>3 testifying?</p> <p>4 MR. SNELL: No, he made a statement on</p> <p>5 the record, so I want to understand it. I</p> <p>6 don't know if Eric and the other Sokol are</p> <p>7 experts, whatever.</p> <p>8 MR. SCHNIEDERS: I can find out for you.</p> <p>9 I was told that they were.</p> <p>10 BY MR. SCHNIEDERS:</p> <p>11 Q. And then over on the far right, you see</p> <p>12 that there are some members of the various advocacy</p> <p>13 groups, AUA, AUGS. Do you see over there, do you know</p> <p>14 Rebecca Rogers?</p> <p>15 A. I do.</p> <p>16 Q. Do you know Dee Fenner?</p> <p>17 A. I do.</p> <p>18 Q. Do you know Anton Bueschen?</p> <p>19 A. I do not.</p> <p>20 Q. John Barry?</p> <p>21 A. I do not.</p> <p>22 Q. Are you a member of AUA?</p> <p>23 A. I'm not a urologist. I am not.</p> <p>24 Q. But fair to say that there's many names</p>

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<p>1 on here that you're familiar with and that are 2 colleagues of yours, correct? 3 A. They are. Again, I don't know the 4 context. I don't know that this is just simply a list 5 of people to be aware of. So Rebecca Rogers probably 6 at the time that this was published was the president 7 maybe of AUGS. Maybe this is someone that they just 8 want people to be aware of the names or if they saw 9 them, they would introduce themselves. Maybe this is 10 somebody that they were hoping to have a better 11 relationship with. I think -- I mean, the fact that 12 they considered me to be an inventor I think they're 13 being very generous or liberal in how they're -- I 14 think they're just categorizing people, which is 15 certainly innately human to take things and put them 16 into nice little boxes. 17 Q. Interesting. But as of February of 18 2008, you had done some consulting with Ethicon, hadn't 19 you? 20 A. I had, yes. 21 Q. And if you go there's several pages of 22 these types of categories, the one I was reading off of 23 was "Incontinence." The next one is "Incontinence 24 (Urologist)," and then after that there's a section</p>	<p>1 Q. And then there's some other names that 2 we saw on the other page, but then there's a couple new 3 ones under "Published" and "Academic." You see a 4 couple that are Goldman. 5 You see that? 6 A. On the same page? 7 Q. On the same page. If you go to 8 "Published," the second -- sorry, the third name down 9 and on "Academic" is Goldman? 10 A. Yes. 11 Q. Do you know Howard Goldman? 12 A. I do. 13 Q. Howard Goldman was one of the authors of 14 the AUGS mesh statement, correct? 15 A. I will accept that if you tell me that, 16 yes. I don't have a visual picture of the author list. 17 Q. And just so -- 18 A. Are we certain that that's the same 19 Goldman? It's fairly common. 20 MR. SNELL: How about object, 21 foundation. Go ahead and lay that for me. 22 BY MR. SCHNIEDERS: 23 Q. So to spell it out for all of you, my 24 next question on the next page under "Expert User,"</p>
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<p>1 called "Pelvic Floor Specialist," which is also a 2 specialty that I believe you would probably hold 3 yourself out as holding, correct? 4 MR. SNELL: Form. 5 THE WITNESS: You know, I mean, the 6 specialty has gone by many names. I think here 7 they were trying to be inclusive, you know, of 8 urology, at the time what we called 9 urogynecology, colorectal, perhaps. 10 BY MR. SCHNIEDERS: 11 Q. But if you look at the page where you'll 12 have some names that are pelvic floor specialists on 13 the next page from where you are, I believe, you made 14 the list. You're an expert user down there? 15 A. I am. Where am I? Oh, there we are. 16 Q. Third from the bottom down there. 17 A. It's a miss -- I don't know who 18 Dr. Tolia is, but that could be me. 19 Q. I think it's you. 20 A. I would not object to that. 21 Q. And do you know a Dr. Fagan? 22 A. He was my partner. 23 Q. That would make a lot of sense. 24 A. Yeah.</p>	<p>1 it's spelled out as Howard Goldman. What is the group 2 CCF? Do you know what the group CCF is? 3 A. I can guess. I can't tell you that I 4 recognize those initials. 5 Q. Well, I'm not going to hold you to it. 6 I'm just curious, can you guess for me? 7 A. My guess would be Cleveland Clinic 8 Foundation. 9 Q. And does Howard Goldman work at 10 Cleveland Clinic? 11 A. I believe so. 12 MR. SNELL: Can we take a break in a 13 minute? 14 MR. SCHNIEDERS: I'm switching topics, 15 so let's take a break. 16 (Brief recess taken at 5:02 p.m.) 17 (Deposition resumes at 5:12 p.m.) 18 BY MR. SCHNIEDERS: 19 Q. I'm going to mark as Exhibit 13 an 20 e-mail chain that you were included on, Doctor. 21 (Document marked for identification as 22 Toggia Deposition Exhibit No. 13.) 23 BY MR. SCHNIEDERS: 24 Q. Do you recall earlier when we were</p>

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<p>1 discussing the concept of whether or not funding from 2 industry or other funding might lead to a conflict of 3 interest. 4 Do you recall that discussion? 5 A. I do. 6 Q. Okay. You can take a minute, if you 7 want, to read that bottom e-mail so you have some 8 context here, and I'm going to ask you if you recall 9 this? 10 A. I mean, I'm aware of the -- you know, 11 the discourse between two of my colleagues. Are you 12 asking me specifically am I aware of the e-mail or just 13 of the circumstances? 14 Q. Either one. 15 A. I'm aware of the circumstances. I don't 16 recall whether this was covered in the TVT deposition 17 or not. 18 Q. You guys covered a lot of stuff that 19 never made it to the record, and that's impressive. 20 You were on this e-mail? 21 A. Well, I was copied on this e-mail, okay, 22 right. 23 Q. Right. And what, to your knowledge, was 24 this consternation about?</p>	<p>1 Q. Do you know why you would have been 2 included on this e-mail? 3 A. I don't, no. 4 Q. And Dr. Lucente is a colleague of yours. 5 Do you consider him to be a friend as well, or is it 6 somewhere in that blurred line? 7 A. I think it's fair to say that -- I've 8 known Vince since he was a fellow, so we go back at 9 least 25 years. Vince is certainly both a colleague 10 and a friend of mine, as is Dr. Iglesias, who I've 11 known for about the same amount of time as well, I knew 12 her when she was a fellow as well. 13 Q. Fair enough. Set that to the side. 14 A. You understand that Dr. Lucente and I 15 are both Italian, and so sometimes that may influence 16 the tone in which we respond to other people, and we're 17 both from New York. 18 (Document marked for identification as 19 Toggia Deposition Exhibit No. 14.) 20 BY MR. SCHNIEDERS: 21 Q. Give you what's been marked as Exhibit 22 14. Unfortunately, this is the method by which we get 23 this information a lot of times. I want you to look at 24 this, and I'll give you an opportunity if you need to</p>
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<p>1 A. If I remember correctly, and this, of 2 course, is going back for six years, and this is a 3 relatively minor issue that I think Dr. Iglesia had 4 either responded in a letter to the editor, it could 5 have even have been -- you know, when we present things 6 at national meeting, we allow people to get up, make 7 comments, suggestions. So in one of these forums, she 8 was trying to -- and I can't remember which way it 9 went, whether it was Lucente initially commenting to 10 Iglesias on her work or whether it was Iglesias 11 commenting to Lucente, but all I can tell you is that I 12 recall that there was some friction and really just 13 collegial -- or not collegial, but discourse between 14 two colleagues about that interaction. 15 Q. Fair to say that Dr. Iglesias inferred 16 that Dr. Lucente's superior outcomes were perhaps due 17 to financially driven bias? 18 MR. SNELL: Objection, calls for pure 19 speculation what somebody else thought. 20 THE WITNESS: I don't know. I'm sorry, 21 but I don't know what study or whether this was 22 written comments, comments in the cafeteria, 23 comments with someone on the podium. 24 BY MR. SCHNIEDERS:</p>	<p>1 vet it in any way, shape or form as I go through some 2 of these, but I will tell you if I found one that's a 3 duplicate, but this is a report that was given to us as 4 part of a larger spreadsheet and it's been reduced just 5 down to your name instead of the thousands of columns 6 and everything like that, and it shows that from 7 March 1st of 2008 through February 2nd of 2010 that 8 Ethicon paid you \$152,000. 9 Do you have any reason to dispute that? 10 MR. SNELL: I'm going to object. That 11 is purely without foundation. You're making a 12 bald-faced assumption based on contract 13 amounts. Do not make a statement on the record 14 that Ethicon paid him that amount of money 15 without proper foundation. And this was 16 explicitly covered in the first deposition too. 17 MR. SCHNIEDERS: I've got several of 18 these. 19 MR. SNELL: You know how much he was 20 paid. You know how much he was paid. You have 21 the productions of how much he was paid. 22 MR. SCHNIEDERS: I have this. 23 MR. SNELL: No, no, no. You have the 24 productions of how much he was paid in each</p>

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<p>1 year.</p> <p>2 MR. SCHNIEDERS: Make your objections.</p> <p>3 MR. SNELL: Don't make a ridiculous --</p> <p>4 lacks foundation.</p> <p>5 MR. SCHNIEDERS: Then make the lacks</p> <p>6 foundation objection.</p> <p>7 THE WITNESS: I don't -- I never</p> <p>8 received \$81,000 from Ethicon in any given</p> <p>9 year. If I looked at this, I would say it's</p> <p>10 more like the number to the far left. I mean,</p> <p>11 I don't know what the two columns mean, but to</p> <p>12 be honest with you, and we did cover this in</p> <p>13 the other deposition, you know, the most I ever</p> <p>14 got paid from Ethicon in a given year might</p> <p>15 have been \$31,000, but, no, \$81,000 no;</p> <p>16 \$45,000, no.</p> <p>17 BY MR. SCHNIEDERS:</p> <p>18 Q. Okay. So this is incorrect, this</p> <p>19 spreadsheet?</p> <p>20 A. I don't know what this represents, so</p> <p>21 how do I say if it's correct or incorrect. I just see</p> <p>22 numbers on a page. I don't -- and I'm being very</p> <p>23 honest with you, that does not resemble anything in my</p> <p>24 working memory.</p>	<p>1 \$153,000. As you can see the requesters, the contract</p> <p>2 amounts are different than what you just saw, as are</p> <p>3 the dates. So is it your testimony -- that in 2010 and</p> <p>4 2011 that this \$153,000 is incorrect?</p> <p>5 MR. SNELL: Form, lacks foundation.</p> <p>6 Go ahead.</p> <p>7 THE WITNESS: I honestly don't recognize</p> <p>8 any of this. I can tell you that often times</p> <p>9 in the contract, there was a ceiling, so it</p> <p>10 would say something like, in a given year, you</p> <p>11 know, your compensation will not exceed, and so</p> <p>12 these numbers like \$30,000, \$10,000, in my</p> <p>13 mind, might have been a ceiling. I just, you</p> <p>14 know, I mean, if you said to me, you know, in</p> <p>15 your relationship with Ethicon between 1999 and</p> <p>16 2011 was your total compensation the 153? I</p> <p>17 mean, maybe. I mean, is this just accounting</p> <p>18 on how they sort of -- but, yeah, I don't know.</p> <p>19 BY MR. SCHNIEDERS:</p> <p>20 Q. That's fine. I just want to get your</p> <p>21 testimony on it. That's fine.</p> <p>22 MR. SNELL: You've already testified in</p> <p>23 the first deposition.</p> <p>24 THE WITNESS: Yes, I did. Okay. That's</p>
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<p>1 Q. Okay. So, sitting here today, your</p> <p>2 testimony is that \$152,000 for that time period doesn't</p> <p>3 look like that was the right amount?</p> <p>4 A. Over the course of two -- over the</p> <p>5 course of two years.</p> <p>6 Q. From March 1st of '08 through</p> <p>7 February 2nd of 2010.</p> <p>8 A. No, this suggests that between -- that</p> <p>9 between -- right, March 1st of 2008 to March 1st, 2009</p> <p>10 they paid me \$81,000, no, no, not even -- not even --</p> <p>11 no.</p> <p>12 Q. You dispute that amount?</p> <p>13 MR. SNELL: He already told you.</p> <p>14 THE WITNESS: Yes.</p> <p>15 (Document marked for identification as</p> <p>16 Toglia Deposition Exhibit No. 15.)</p> <p>17 BY MR. SCHNIEDERS:</p> <p>18 Q. I'm going to mark as Exhibit 15 the next</p> <p>19 spreadsheet we had for this. I actually handwrote the</p> <p>20 Bates number on that one since they come from the Excel</p> <p>21 spreadsheet.</p> <p>22 This one covers -- and it just had end dates on</p> <p>23 this spreadsheet, but the end dates are September 23rd</p> <p>24 of 2010 through November 5th of 2011, and that covers</p>	<p>1 fine.</p> <p>2 MR. SNELL: You don't have to accept it.</p> <p>3 MR. SCHNIEDERS: Nobody is accepting. I</p> <p>4 said all I said we're doing is getting your</p> <p>5 testimony.</p> <p>6 THE WITNESS: That's fine.</p> <p>7 (Document marked for identification as</p> <p>8 Toglia Deposition Exhibit No. 16.)</p> <p>9 BY MR. SCHNIEDERS:</p> <p>10 Q. Exhibit 16 is Master Consulting</p> <p>11 Agreement. This one covers the time period that starts</p> <p>12 on February 1st of 2011 and ends on March 31st of 2012.</p> <p>13 It may have been a few years since you've looked at one</p> <p>14 of these doctor, but if you go back to Exhibit A,</p> <p>15 that's where it talks about what the fees are</p> <p>16 associated with it?</p> <p>17 A. I'm sorry. Would you mind giving me a</p> <p>18 few more minutes to just --</p> <p>19 Q. If you look at Exhibit A, there's boxes</p> <p>20 checked that cover this contract right here, and the</p> <p>21 first one is --</p> <p>22 A. I apologize. I'm not with you. Can you</p> <p>23 tell me again where you are.</p> <p>24 Q. Exhibit A.</p>

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<p>1 A. Sure.</p> <p>2 Q. It's about three-fourths of the way</p> <p>3 through this, I would say. The bottom number on the</p> <p>4 Bates number ends with 167.</p> <p>5 A. Yes, okay. Sorry. Go ahead.</p> <p>6 Q. Under A it says, "Consultant agrees to</p> <p>7 perform the Services below for which the 'Yes' box is</p> <p>8 checked for the compensation set forth therein."</p> <p>9 Company-sponsored speaker programs is checked yes, and</p> <p>10 then if you read through there it says, "Consultant</p> <p>11 shall present scientific, clinical and related</p> <p>12 professional information by speaking at</p> <p>13 Company-sponsored seminars and meetings as requested by</p> <p>14 Company. Consultant shall disclose to attendees that</p> <p>15 he is being compensated by Company for the</p> <p>16 presentation. Consultant shall make such presentations</p> <p>17 on 8 occasions. The presentation will review stress</p> <p>18 urinary incontinence procedures. For each such</p> <p>19 speaking engagement, Company shall pay consultant</p> <p>20 \$3,000 per 8 hour day plus reasonable out-of-pocket</p> <p>21 expenses.</p> <p>22 And I'll tell you that eight times 3,000 is</p> <p>23 \$24,000. It says no under Subsection 2. It says no</p> <p>24 under Subsection 3. Under Subsection 4 it says</p>	<p>1 And then it goes down to say "B. The parties</p> <p>2 agree that compensation paid to consultant shall not</p> <p>3 exceed \$54,000 per contract term, except as may be</p> <p>4 mutually agreed in writing by the Parties."</p> <p>5 Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. Do you recall this contract?</p> <p>8 A. Yes.</p> <p>9 Q. So with counsel's caveat that these --</p> <p>10 saying that these are agreed maximums, not payments</p> <p>11 that are made out, I'm keeping a running list of these</p> <p>12 amounts here.</p> <p>13 A. All right. Can I point out that the</p> <p>14 numbers you provided on this list for the period of</p> <p>15 time covered in this contract greatly exceed this</p> <p>16 \$54,000, which is one of the reasons why I don't</p> <p>17 believe that this represents actual compensation.</p> <p>18 Q. Sure, but you can also point out the</p> <p>19 fact that the dates and contracts often coincide at the</p> <p>20 same time because there's different consulting</p> <p>21 agreements that you signed at different times with</p> <p>22 different people, correct?</p> <p>23 MR. SNELL: Form, foundation.</p> <p>24 THE WITNESS: Can I disagree with you,</p>
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<p>1 "Preceptorship/Surgical Training, yes. Consultant</p> <p>2 shall allow visiting surgeons and visiting Company</p> <p>3 sales representatives to observe surgical procedures</p> <p>4 involving the practice of stress urinary incontinence,</p> <p>5 the clinical uses of stress urinary incontinence family</p> <p>6 of products and to consult with Consultant regarding</p> <p>7 such procedures applicable to patient confidentiality</p> <p>8 and consent requirements. In particular, Consultant</p> <p>9 agrees he or she shall secure appropriate patient</p> <p>10 consent to the presence of any third party during</p> <p>11 surgical training programs as necessary. Consultant</p> <p>12 shall allow such visits up to 9 occasions, and Company</p> <p>13 shall pay consultant \$3,000 for each such session per 8</p> <p>14 hour day."</p> <p>15 And that adds up, if you take nine times 3,000,</p> <p>16 to 27,000.</p> <p>17 If you go to the next page, it's checked no on</p> <p>18 Number 5, 6, 7. On 8 Other, it's checked as yes, and</p> <p>19 it says, Consultant shall perform other services</p> <p>20 designated below for, and it has a dollar sign and it</p> <p>21 says varies per hour, and the description of services</p> <p>22 is faculty training meetings and educational</p> <p>23 summits/forums. Negotiated rate to be no more than a</p> <p>24 maximum of \$375 rate/per hour.</p>	<p>1 because this document specifically refers to</p> <p>2 this as a Master Consulting Agreement, and</p> <p>3 everything on this list right here is</p> <p>4 designated under the Master Consulting</p> <p>5 Agreement. So these two documents don't agree.</p> <p>6 I mean, this is a completed document, and I</p> <p>7 have recollection. I have no idea where these</p> <p>8 numbers came from.</p> <p>9 BY MR. SCHNIEDERS:</p> <p>10 Q. Fair to say that you don't believe in</p> <p>11 any given year you made over \$100,000 from Ethicon?</p> <p>12 A. I think \$31,000 was the highest I made,</p> <p>13 and I will tell you that that was when we were working</p> <p>14 on the PASS study. That had nothing to do with other</p> <p>15 stuff.</p> <p>16 (Document marked for identification as</p> <p>17 Toggia Deposition Exhibit No. 17.)</p> <p>18 BY MR. SCHNIEDERS:</p> <p>19 Q. I'll keep going through and you can</p> <p>20 disagree with me on the numbers, that's fine, I'm just</p> <p>21 putting them on the record. This is 17.</p> <p>22 A. Fine.</p> <p>23 Q. And this is part of an e-mail that is</p> <p>24 titled Action Required with some numbers 2012 Master</p>

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<p>1 Consulting Agreement, Marc Toglia, MD, Incontinence 2 Annual, and it's some other contract numbers there. 3 It says under here under line items, Number 1, 4 Marc Toglia, MD, and then it says consulting fee. It's 5 got a contract ID number, which if you want to 6 reference it on the spreadsheet over there doesn't show 7 up anywhere, and it's got an amount of \$14,250. I'm 8 not asking if it's accurate. I'm asking if I read that 9 correctly. 10 A. This is for 2012. I don't recall 11 receiving -- I don't know that I received any 12 compensation from them. I think this might be the 13 amount that I was approved, the maximum amount. I have 14 no idea. I have no idea what this refers to. 15 Q. And you see down at the bottom that the 16 total cost of this contract is \$15,000. 17 Do you see that? 18 A. Yes. 19 Q. You can set that to the side. Give you 20 what I'm marking as Exhibit 18, which is another 21 consulting agreement. 22 (Document marked for identification as 23 Toglia Deposition Exhibit No. 18.) 24 BY MR. SCHNIEDERS:</p>	<p>1 and that was for four occasions at \$3,000, and then 2 moving to the end, everything else was checked no, and 3 "The Parties agree that compensation paid to consultant 4 shall not exceed \$15,000 per contract term, except as 5 may be mutually agreed by the Parties." 6 Do you see that? 7 A. Yes. 8 Q. So I will tell you that I have gone to 9 add up the amounts, and the amounts that I've added up 10 from the spreadsheets and from these contracts we've 11 been looking at after going through to make sure that 12 the contract numbers didn't duplicate was \$389,000? 13 A. Sir, this was -- 14 MR. SNELL: You got to let me object. 15 Objection, lacks foundation. 16 MR. SCHNIEDERS: Everybody has to let me 17 ask my question first. That's how this works. 18 THE WITNESS: Fair enough. 19 BY MR. SCHNIEDERS: 20 Q. I have gone through and added up the 21 amounts from the spreadsheets and from the contracts 22 and made sure that they didn't duplicate any contract 23 numbers, and it comes up to an amount of \$389,000. I 24 think what you're going to tell me is that you were</p>
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<p>1 Q. This takes a slightly different form 2 than the one we were looking at that was the master 3 agreement, correct? 4 A. Yes. 5 Q. Although, if you go through, you'll see 6 that when it gets to the third page, it starts to look 7 a little bit more like the Master Consulting Agreements 8 that we've seen before. On this one the agreement 9 shall commence on April 1st, 2012 and then it goes 10 through March 31st of 2013. 11 It is nearly identical in content. If you go 12 to the page where you signed it, you signed it on 13 February 6th of 2012. 14 Do you see that? 15 A. Yes. 16 Q. And Paul Parisi who is countersigned, do 17 you know who Paul Parisi is? 18 A. He is an individual that worked for 19 Ethicon. 20 Q. And on this one on the Exhibit A, it 21 appears that there was a yes checked next to 22 company-sponsored speaking program again, and it was 23 for one occasion for \$3,000, and then the Number 4 the 24 preceptorship/surgical training was checked as well,</p>	<p>1 never paid \$389,000 from Ethicon? 2 MR. SNELL: My objection is lacks 3 foundation, misstates the evidence. 4 THE WITNESS: What do you think that 5 number represents? I don't understand. That 6 was the maximum that I could have done. I can 7 tell you, say specifically the first thing 8 talked about giving presentations at a national 9 meeting, or, you know, I can't -- other than -- 10 I can't tell you that I ever was asked to give 11 that kind of a presentation. So even though it 12 says I could have given that presentation, 13 pretty much the only thing that I ever did in 14 prof ed was teach cadaver labs, which maybe 15 occurred once or twice a year, okay, or I 16 precepted an individual, which, on average, may 17 have occurred two to six times a year. That 18 was probably -- you know, again, this might 19 have been an allowance. You know, the company 20 was approving a maximum amount. That does not 21 reflect what I was paid by the company. 22 BY MR. SCHNIEDERS: 23 Q. I think you said, I just was looking at 24 the record, you said that probably the most you ever</p>

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<p>1 got paid in any given year was 31,000?</p> <p>2 A. My -- yes, my recollection from the</p> <p>3 earlier deposition, and, again, this may not be</p> <p>4 accurate, my recollection was that in 2011, I received</p> <p>5 \$31,000, and my recollection is that that related to</p> <p>6 the period of time that I was working on product</p> <p>7 development. It did not reflect preceptor time,</p> <p>8 lecturing time. That was never a big part of my role</p> <p>9 with the company.</p> <p>10 Q. Okay. I'm going to mark as Exhibit 19</p> <p>11 this e-mail string.</p> <p>12 (Document marked for identification as</p> <p>13 Toglia Deposition Exhibit No. 19.)</p> <p>14 BY MR. SCHNIEDERS:</p> <p>15 Q. We can certainly look at the top e-mail</p> <p>16 here in a moment, but it doesn't pertain to what we're</p> <p>17 here to talk about, but if you go down to the bottom,</p> <p>18 Ronald Horton writes an e-mail.</p> <p>19 Do you know who Ronald Horton is?</p> <p>20 A. No.</p> <p>21 Q. But it says he's with ETHUS, which I</p> <p>22 believe is Ethicon US. He's written it to a Marti</p> <p>23 Heckman, Alyson Wess, Lissette Caro-Rosado, Paul Parisi</p> <p>24 and Matt Henderson.</p>	<p>1 think about that.</p> <p>2 THE WITNESS: I'm sorry. Me tell him</p> <p>3 what I think about --</p> <p>4 MR. SNELL: You can answer. I'm not</p> <p>5 sure if there's a question. The question was</p> <p>6 so someone at US group, product director Ronald</p> <p>7 believes you were pay \$153,000.</p> <p>8 MR. SCHNIEDERS: In 2010.</p> <p>9 MR. SNELL: In 2010.</p> <p>10 THE WITNESS: I'm pretty confident that</p> <p>11 I didn't receive anything like that, sorry.</p> <p>12 BY MR. SCHNIEDERS:</p> <p>13 Q. So this e-mail is just wrong?</p> <p>14 A. I don't know, sir. I was not part of</p> <p>15 this e-mail.</p> <p>16 Q. Well, I understand that, Doctor. What</p> <p>17 I'm saying is it says that you were paid \$153,000 in</p> <p>18 2010. You're saying you weren't, so it's wrong, right?</p> <p>19 MR. SNELL: Lacks foundation.</p> <p>20 THE WITNESS: Yes, I'm telling you that</p> <p>21 I did not receive that compensation.</p> <p>22 BY MR. SCHNIEDERS:</p> <p>23 Q. Does that mean that your group received</p> <p>24 that compensation?</p>
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<p>1 A. Right.</p> <p>2 Q. Now, we've already talked about Paul</p> <p>3 Parisi.</p> <p>4 Do you recognize any of those other names?</p> <p>5 A. Vaguely.</p> <p>6 Q. And the subject is KOL Usage, which, as</p> <p>7 we established before, is a term used in industry?</p> <p>8 A. Yes.</p> <p>9 Q. And it means most likely key opinion</p> <p>10 leader, and Ronald Horton writes, "All, please see the</p> <p>11 below list of highly used KOLs and the total pay they</p> <p>12 have received this year." This is written on Friday,</p> <p>13 November 19th, 2010?</p> <p>14 A. Uh-huh.</p> <p>15 Q. And if you look at the second page, it</p> <p>16 says Toglia total, \$153,000.</p> <p>17 A. No.</p> <p>18 Q. So someone at US group product director</p> <p>19 for uterine health, Ronald Horton believes that you</p> <p>20 were paid \$153,000 in 2010?</p> <p>21 MR. SNELL: Object on the foundation,</p> <p>22 calls for speculation. Also, I think this</p> <p>23 e-mail was marked and covered in the earlier</p> <p>24 deposition, but go ahead, tell him what you</p>	<p>1 A. No.</p> <p>2 Q. Did anyone on your behalf receive that</p> <p>3 compensation?</p> <p>4 A. No, not to my knowledge.</p> <p>5 MR. SCHNIEDERS: Marking as Exhibit 20</p> <p>6 this e-mail string.</p> <p>7 (Document marked for identification as</p> <p>8 Toglia Deposition Exhibit No. 20.)</p> <p>9 BY MR. SCHNIEDERS:</p> <p>10 Q. I'll let you familiarize yourself with</p> <p>11 it, the e-mail from Joy de los Reyes on down is the one</p> <p>12 I'm talking about. The very bottom one is an e-mail</p> <p>13 from you.</p> <p>14 So, Doctor, this is an e-mail that you wrote</p> <p>15 from your e-mail address that we will make sure doesn't</p> <p>16 show up anywhere it's not supposed to, to Melissa</p> <p>17 Chaves.</p> <p>18 Are you familiar with Melissa Chaves?</p> <p>19 A. I recognize the name. I honestly</p> <p>20 can't -- I don't know what role she plays in the</p> <p>21 company.</p> <p>22 Q. The subject is "thanks," and it says,</p> <p>23 Melissa, I wanted to thank you again for including me</p> <p>24 on the sling discussion panel yesterday. I very much</p>

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<p>1 enjoy working on these types of panels and did 2 appreciate what the others had to say on the other 3 approaches. It's fascinating how different approaches 4 work equally well in different hands. Thought it went 5 very well, and I received a lot of positive feedback 6 afterwards from the audience. I think that everyone 7 felt that it was fairly balanced, and several folks 8 mentioned that they were glad to see that Ethicon is 9 still very much supportive of the retropubic design, as 10 many feel it is still your best product.</p> <p>11 That said, it has occurred to me that your 12 company spends virtually no time on TVT-R training, and 13 this is something you may want to consider revisiting, 14 especially as you look to bring surgeons back to the 15 TVT family of products.</p> <p>16 Now, when you said "bring surgeons back to the 17 TVT family of products," what did you mean?</p> <p>18 A. Okay. So my recollection of the 19 contents of this discussion is that Ethicon held a 20 meeting of faculty members. As part of that meeting, 21 they asked three of us to volunteer to do a 22 debate-style discussion. I represented the retropubic 23 approach. Another doctor represented the obturator 24 approach. The third doctor represented the TVT Secur</p>	<p>1 in further -- they wanted to invite me to give a 2 further debate or another talk in front of my 3 colleagues that I enjoyed participating in that type of 4 activity.</p> <p>5 Q. So you wrote this in order to help 6 Ethicon bring surgeons back to the TVT family of 7 products, right?</p> <p>8 MR. SNELL: Objection, misstates.</p> <p>9 THE WITNESS: No, no. I just -- you 10 know, I just thanked them. I was not paid 11 separately to participate in the debate. I was 12 just thanking them for thinking of me as a -- 13 as somebody who could speak in a debate fashion 14 on this topic. And, again, my feeling was is 15 that the TVT sling had the most data out there 16 relative to other retropubic products, and I 17 felt quite confident that this was the product 18 that was -- according to the data, had the most 19 efficacy and safety and just, you know, the 20 amount of data presented and that I thought 21 that they -- if they focused on presenting that 22 data the way that I did in the debate, that 23 hopefully others would also see that the TVT is 24 the best procedure based upon sound science for</p>
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<p>1 approach. They then presented us with a patient case 2 and then asked us to defend why we would choose 3 whatever approach we were assigned to. My recollection 4 is that I was assigned to the retropubic approach. It 5 was kind of a debate style amongst colleagues. 6 Everybody I thought did a very good job of defending 7 the position that they were asked to represent.</p> <p>8 Again, it was a -- it was a debate so we were 9 just asked to defend our position, and at the end of 10 that debate, people commented to me that they thought 11 that my argument for that particular case for the 12 debate was very convincing. As you well know, the 13 majority of what I do in my clinical practice is the 14 TVT retropubic approach. As my expert report 15 previously illustrated, I believe that that is the 16 product that has the most data of any procedure for 17 incontinence in our history and that that represents 18 very solid data, and so obviously I feel very strongly 19 that that is the procedure of choice. That's my 20 opinion.</p> <p>21 So I was commenting to them that, you know, my 22 opinion was that they should spend more time, you know, 23 training and talking about this thing, and I just 24 simply told them that I would be happy to participate</p>	<p>1 the treatment of stress incontinence across the 2 entire spectrum of the disease, mixed 3 incontinence, plain stress incontinence, repeat 4 surgery, et cetera.</p> <p>5 Q. And you wrote here, "Certainly, users of 6 other retropubic products could be persuaded, and 7 perhaps those using obturator approaches could be asked 8 if they would like to add the retropubic approach for 9 their more complicated patients, (eg expand upon their 10 skill set, now that they are comfortable with TOT.) 11 From there, it might be easier to re-explore the 12 possibility of them using your brand of obturator 13 sling."</p> <p>14 So it's a sales pitch, right?</p> <p>15 MR. SNELL: Objection.</p> <p>16 THE WITNESS: I was speaking to a 17 salesperson. I again was trying to use 18 language. I don't sell anything myself. I 19 have no vested interest in what they get 20 revenue wise. I certainly don't see any of it. 21 I was just defending TVT retropubic as the gold 22 standard in our field and just wanted to let 23 them know that I thought that that was -- you 24 know, in my opinion, as a minor player, you</p>

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<p>1 know, in this world for them, that this is</p> <p>2 where I thought I was most passionate about,</p> <p>3 and, again, I was speaking to the data and the</p> <p>4 science, that to me this was a no brainer. You</p> <p>5 know, you should try to reengage people based</p> <p>6 on the science and the data.</p> <p>7 Q. And you offered to do a dinner talk on</p> <p>8 the merits, correct?</p> <p>9 A. Yes. That might have been with other</p> <p>10 members of her team. I don't know.</p> <p>11 Q. Sure. But you're compensated for dinner</p> <p>12 talks as a teacher, correct?</p> <p>13 A. If I was speaking to -- I mean, I was</p> <p>14 not -- like I said, I was not compensated for this</p> <p>15 participation. If I had dinner with them locally, I</p> <p>16 don't get paid for that kind of stuff. Again, I'm just</p> <p>17 an advocate for the TVT retopublic approach. I thought</p> <p>18 that I made a strong argument why the data supports the</p> <p>19 retopublic approach as the best procedure. I got a lot</p> <p>20 of positive feedback that my analysis was very</p> <p>21 convincing, and given that that's one of my strengths,</p> <p>22 the ability to read the data as I presented here</p> <p>23 independently and articulate a comparison, I was simply</p> <p>24 offering that, and that's all I remember.</p>	<p>1 just saw on that other e-mail regarding the top used</p> <p>2 KOLs, but down below that, there's an e-mail from a</p> <p>3 gentleman named Scott Jones.</p> <p>4 Do you know Scott Jones?</p> <p>5 A. Yes.</p> <p>6 MR. SNELL: Counsel, I think you</p> <p>7 identified this as Exhibit 22, but I think it's</p> <p>8 21, just so we get a clear record. You started</p> <p>9 off on 21 and then you said 22.</p> <p>10 MR. SCHNIEDERS: It's 21.</p> <p>11 BY MR. SCHNIEDERS:</p> <p>12 Q. So under here it says there's a heading</p> <p>13 that says "Convention Updates," and then it says, "AUGS</p> <p>14 was another huge success."</p> <p>15 Does AUGS have a convention every year?</p> <p>16 A. No. AUGS has an annual scientific</p> <p>17 meeting.</p> <p>18 Q. Okay.</p> <p>19 A. Understand that industry looks at these</p> <p>20 things different than how we look at it.</p> <p>21 Q. I can believe that.</p> <p>22 A. Right.</p> <p>23 Q. "The day prior to the official meeting</p> <p>24 start, we hosted 2 educational events for urogyn</p>
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<p>1 Q. Okay.</p> <p>2 MR. SCHNIEDERS: I'll object and move to</p> <p>3 strike that last answer as nonresponsive, and,</p> <p>4 Doctor, if we don't keep it down to -- because</p> <p>5 I'm running out of time but...</p> <p>6 THE WITNESS: I'm sorry that you don't</p> <p>7 like my answer, but that's my answer.</p> <p>8 BY MR. SCHNIEDERS:</p> <p>9 Q. I asked you if you were compensated for</p> <p>10 dinner meetings. I don't think that was responsive.</p> <p>11 A. I don't think I've ever been</p> <p>12 compensated. I don't think I've ever been compensated</p> <p>13 for a dinner meeting. I don't think I've ever been</p> <p>14 invited to participate in a dinner meeting.</p> <p>15 (Document marked for identification as</p> <p>16 Toggia Deposition Exhibit No. 21.)</p> <p>17 BY MR. SCHNIEDERS:</p> <p>18 Q. This is Exhibit 21.</p> <p>19 MR. SNELL: I'm reading the transcript</p> <p>20 where he does say.</p> <p>21 BY MR. SCHNIEDERS:</p> <p>22 Q. So, anyway, this is Exhibit 22, and this</p> <p>23 is another e-mail chain and, again, if you look at the</p> <p>24 very top, it's got Ronald Horton on it again, who we</p>	<p>1 fellows. These events are part of our fellowship</p> <p>2 education strategy being led by Jen Paradise, and</p> <p>3 fellow directors are taking of EWHU's involvement."</p> <p>4 And then the second bullet point or a line point there</p> <p>5 says, "The Prosima & TVT Exact symposium was well</p> <p>6 attended and highlights another success led by</p> <p>7 Dr. Toggia & Dr. Garris."</p> <p>8 Do you remember presenting at the Prosima and</p> <p>9 TVT Exact symposium at AUGS in 2010?</p> <p>10 A. I would have presented the TVT Exact</p> <p>11 module of that. I would not have presented the</p> <p>12 Prosima.</p> <p>13 Q. And you would have been there on behalf</p> <p>14 of Ethicon, correct?</p> <p>15 A. Typically, if I'm remembering the event,</p> <p>16 I think this was a industry sponsored lunch, and during</p> <p>17 the lunch hour, they provided lunch for whatever it is,</p> <p>18 20 or 30 participants, and I would have given, you</p> <p>19 know -- as you know, I was involved in the development</p> <p>20 of TVT Exact, and so I would have provided some kind of</p> <p>21 an update, you know, or some kind of just general</p> <p>22 educational talk, as we've provided here.</p> <p>23 Q. And you would have been compensated for</p> <p>24 that, correct?</p>

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<p>1 A. Yes, I would have thought so.</p> <p>2 Q. And this was in 2010, which was the year</p> <p>3 that we saw the e-mail where they say you were paid</p> <p>4 \$153,000, correct?</p> <p>5 MR. SNELL: Foundation.</p> <p>6 THE WITNESS: I will -- what's the date</p> <p>7 here? I would say the event occurred in 2010.</p> <p>8 (Document marked for identification as</p> <p>9 Toglia Deposition Exhibit No. 22.)</p> <p>10 BY MR. SCHNIEDERS:</p> <p>11 Q. I'm going to hand you what I'm marking</p> <p>12 as Exhibit 22. This is an e-mail from a gentleman</p> <p>13 named Kevin Frost.</p> <p>14 Do you know Kevin Frost?</p> <p>15 A. I do not.</p> <p>16 Q. The subject is "2011 Incontinence &</p> <p>17 Pelvic Floor Recap," and then it begins, "Hello all,</p> <p>18 the 2011 Ethicon Women's Health & Urology Incontinence</p> <p>19 and Pelvic Floor Summit was recently held in Sonoma,</p> <p>20 California (March 31-August 2nd)."</p> <p>21 Are you familiar with the incontinence and</p> <p>22 pelvic floor summit that Ethicon would hold annually?</p> <p>23 A. Yes.</p> <p>24 Q. And was it typically in Sonoma, or did</p>	<p>1 periodically, so I'm showing you from 2009, you go down</p> <p>2 here where it says Dr. Toglia regarding a TVT panel at</p> <p>3 the summit?</p> <p>4 A. Oh, okay. I see. I'm sorry. Yes.</p> <p>5 Q. And that's in February of 2009?</p> <p>6 A. Yes.</p> <p>7 Q. So you would have been there in February</p> <p>8 of 2009, and then looking at the document we're looking</p> <p>9 at now, this is 2011, correct?</p> <p>10 A. Yes.</p> <p>11 Q. And if you go down it says in the middle</p> <p>12 there a breakdown of this year's attendees are as</p> <p>13 follows, 31 gynos, 31 urogyns (including 4 fellows), 19</p> <p>14 urologists. And then at the very bottom, it says, "a</p> <p>15 special thanks to the following customers who served as</p> <p>16 meeting moderators," and it lists you along with three</p> <p>17 other doctors.</p> <p>18 Do you see that?</p> <p>19 A. Yes. I'm sorry, there are three more</p> <p>20 names on the other page. I understand your point.</p> <p>21 Q. There are three on this page, and then</p> <p>22 there's three additional on the other page?</p> <p>23 A. Three others besides myself, yes.</p> <p>24 Q. And it refers to you as a customer. Do</p>
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<p>1 it move around?</p> <p>2 A. No. I only attended a handful of them.</p> <p>3 This was the only one that I had -- I don't know if</p> <p>4 they had ever been there before. I had only been to</p> <p>5 one that was in Sonoma.</p> <p>6 Q. Just so we're clear on the record here,</p> <p>7 if you go back to exhibit -- it's the e-mail that's</p> <p>8 talking about training around the TVR. You see this</p> <p>9 one, Doctor, Bates ends with 3824.</p> <p>10 What exhibit is that, Doctor?</p> <p>11 A. Exhibit 20 is an e-mail from 2009.</p> <p>12 Q. Okay. So in Exhibit 20, if you'll see</p> <p>13 there it says under the subject "RE: thanks TVTR Prof</p> <p>14 Ed training/summit comments."</p> <p>15 Is it possible that when you met Ms. Chaves</p> <p>16 that that was at the summit?</p> <p>17 A. Excuse me?</p> <p>18 Q. Is it possible that when you met</p> <p>19 Ms. Chaves and then wrote this e-mail that was just</p> <p>20 after the summit?</p> <p>21 A. I'm sorry. I thought the summit was</p> <p>22 2011. This is 2009.</p> <p>23 Q. The summit was every year from my</p> <p>24 understanding, and you said that you only went to it</p>	<p>1 you know why the company would refer to you as a</p> <p>2 customer?</p> <p>3 A. I don't, because I use their products,</p> <p>4 perhaps.</p> <p>5 Q. At the end of the day they're selling</p> <p>6 doctors on using the products, not the patient, right?</p> <p>7 MR. SNELL: Form, foundation.</p> <p>8 MR. SCHNIEDERS: I'll withdraw.</p> <p>9 BY MR. SCHNIEDERS:</p> <p>10 Q. You see where it says customers, and</p> <p>11 it's referring to you and some other of your</p> <p>12 colleagues, correct?</p> <p>13 A. Yes. I don't know, but I don't</p> <p>14 understand why I'm referred to as a customer.</p> <p>15 Q. Okay. Set that to the side.</p> <p>16 MR. SCHNIEDERS: I'm going to mark this</p> <p>17 Exhibit as 23.</p> <p>18 (Document marked for identification as</p> <p>19 Toglia Deposition Exhibit No. 23.)</p> <p>20 BY MR. SCHNIEDERS:</p> <p>21 Q. This will be a very brief question,</p> <p>22 Doctor, and I just want to call your attention to it.</p> <p>23 It says under the subject, "Let me know your</p> <p>24 thoughts... this is a draft." So this e-mail that</p>

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<p>1 we're looking at right here, the second doesn't show 2 that it went to you, but the bottom one down here, the 3 draft itself was a draft of an e-mail to you. 4 Do you see that? 5 A. Okay. 6 Q. And it's from a woman named Rhonda 7 Peebles. 8 Do you know Rhonda Peebles? 9 A. Yes. 10 Q. In that she says, "I am excited to 11 announce that Ethicon Women's Health & Urology received 12 approval for a new TVT sling, Gynecare TVT Exact, and 13 will be launching very quickly. We are putting 14 together 2 key customer events to introduce the product 15 and would love for you to be a part of the launch. You 16 were one of the initial physicians to be exposed to the 17 product via our customer labs last fall so your input 18 would be invaluable." 19 Do you recall if you attended that event? 20 A. I don't even know that I ever received 21 this e-mail. I don't think I attended either of those. 22 I don't recall. 23 Q. Okay. That's fair. Set it aside. 24 Now, would you consider yourself when you're</p>	<p>1 that I taught all three products, that my personal 2 practice was still very much aligned with the 3 retropubic approach, right. 4 Q. And, similarly, your belief in the TVT 5 product has made you an advocate for it because you 6 believe it's the safest option, right? 7 A. Well, I believe that the experience and 8 the publications support the safety and the 9 effectiveness of that product and that it is the most 10 vigorous scientific data that we have for any product 11 in the history of incontinence treatment. 12 Q. But -- and you've advocated for that 13 product and other products you believe in to fellow 14 surgeons when they were talking about it, right? 15 MR. SNELL: Form. 16 THE WITNESS: Specifically that product, 17 yes. 18 BY MR. SCHNIEDERS: 19 Q. But you would never consider anything 20 that you've done to be advertising for Ethicon, right? 21 A. No. 22 MR. SCHNIEDERS: Off the record. 23 (Brief recess taken at 5:59 p.m.) 24 (Deposition resumes at 6:02 p.m.)</p>
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<p>1 working on behalf of Ethicon, not for Ethicon, but on 2 behalf of Ethicon or any other device company to be a 3 salesperson for them? 4 A. Not at all. 5 Q. Okay. Are you an advocate for them? 6 A. I'm an advocate for women's health. I'm 7 an advocate for women that suffer with pelvic floor 8 disorders, and I'm for anything that I can do that 9 helps to increase the awareness of these conditions and 10 treatments for it. As you know, this is a major public 11 health burden, and there are more women that suffer 12 from incontinence and prolapse than we currently have 13 manpower to care for. 14 Q. Earlier when you were talking about the 15 TVT-R panel that you had been part of, you said you 16 were advocating for that approach because you believe 17 that's the best approach, right? 18 A. Understand, I was assigned it, right. 19 So if I had been assigned obturator, my assignment was 20 the same and I would have presented my argument in that 21 regard. That said, I'm sure that they chose me for 22 TVT-R because they knew that despite the fact that 23 other products had been developed, despite the fact 24 that I had participated in trials with TVT Secur and</p>	<p>1 BY MR. SCHNIEDERS: 2 Q. We're back on the record after a short 3 break. Doctor, I'm going to mark as Exhibit 24 an 4 e-mail chain. 5 (Document marked for identification as 6 Toggia Deposition Exhibit No. 24.) 7 BY MR. SCHNIEDERS: 8 Q. And this is from, again, Rhonda Peebles, 9 who we just saw an e-mail from her a moment ago, right? 10 A. Yes. I'm sorry, just reviewing this. 11 Q. And it's to a Lindsay Froelich. 12 Do you know her? 13 A. Do not, no. 14 Q. All right. It starts off, "Sorry for 15 the delay. I've been swamped with launch meeting 16 planning. Feel free to put time on my calendar the 17 week of the 17th to discuss further, Rhonda." 18 And this is in response, if you go to the 19 second page, to questions that Ms. Froelich was asking 20 with regard to TVT Exact. 21 And so she answers several. Under Number 3, a 22 question she's asked is "Is there any clinical data 23 that will be published or presented this year?" And 24 Rhonda Peebles writes back, "There is no specific</p>

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<p>1 clinical data. Exact will leverage data from TVT 2 classic." 3 Is that an accurate statement, to your mind? 4 MR. SNELL: Foundation, speculation. 5 THE WITNESS: I'm sorry, I don't -- I 6 don't see it. Is there two pages? 7 BY MR. SCHNIEDERS: 8 Q. There are two pages. 9 A. Okay. 10 Q. But it's the front page you need look 11 at. You don't need to go back and forth with the 12 questions. They're written above each spot. So go to 13 the first page. 14 A. Oh, I'm sorry. 15 Q. That's okay. If you go to question 3, 16 you will see the question and the answer. 17 A. Okay. Sure. What's your question? 18 Q. So the question written there "Is there 19 any clinical data that will be published or presented 20 this year? Answer, there is no specific clinical data. 21 Exact will leverage data from TVT classic." 22 Do you believe that statement to be true? 23 A. I'm not aware whether data was -- I'm 24 not aware of data being presented that year.</p>	<p>1 lists AUA, AUGS and ICS-IUGA, the advocacy groups, 2 correct? 3 A. Yes. 4 Q. And then are any important advocacy 5 groups you'd like to reach at launch? Do you have any 6 relationships with them already? Good question, we 7 should discuss. 8 And lastly on 9, who do you recommend as 9 internal and external (KOLs) spokespeople for media 10 interviews? Internal, Dr. Aaron Kirkemo. 11 Do you know Aaron Kirkemo? 12 A. Dr. Kirkemo was a -- one of the medical 13 directors for Ethicon women's health at the time. 14 Q. Okay. And then Howard Goldman, the 15 urologist from Cleveland Clinic that we discussed 16 earlier -- 17 A. Yes. 18 Q. -- that is also one of the authors on 19 the AUGS mesh position statement? 20 MR. SNELL: Form. 21 THE WITNESS: Yes. 22 BY MR. SCHNIEDERS: 23 Q. And it says, "although the CC may not 24 allow doctors to participate in PR."</p>
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<p>1 Q. Okay. When she says "Exact will 2 leverage data from TVT classic," what does that mean to 3 you? 4 MR. SNELL: Objection to form. 5 THE WITNESS: How would I know what 6 Ms. Peebles was meaning? I mean, the product 7 is the same. The mesh itself is the same. The 8 modifications that we made to the product is we 9 changed the handle design. We made the trocar 10 thinner. We made the handle disposable. Other 11 than that, there really is no difference. It's 12 sort of -- was sort of a refresh of the 13 product. 14 BY MR. SCHNIEDERS: 15 Q. Under question 5, What do you hope to 16 achieve through PR with this program? Answer, 17 increased awareness during the launch phase. 18 6. What are the important 19 magazines/newsletters you would like to see cover this 20 product? Answer, Urology and OB-GYN throw-away 21 journals. 22 7. There are major medical meetings -- strike 23 that. 7. Are there major medical meetings where you 24 will be unveiling/displaying this product? And it</p>	<p>1 A. Yes. 2 Q. And then lastly it mentions Dr. Marc 3 Toggia, urogyn, Philadelphia. 4 You see that? 5 A. Yeah. 6 Q. Do you recall being approached by Ms. 7 Peebles to be a spokesperson for TVT Exact? 8 A. Yes, I recall that I was asked to help 9 with an article that addressed urinary incontinence in 10 women, treatment options in women, yes. You understand 11 that, again, I was fairly involved in the development 12 of the TVT Exact product and served as -- I think the 13 video on the surgical steps is myself, you know, 14 demonstrating the procedure, so yes. 15 MR. SCHNIEDERS: I'm going to mark as 16 Exhibit 25. 17 (Document marked for identification as 18 Toggia Deposition Exhibit No. 25.) 19 BY MR. SCHNIEDERS: 20 Q. This document that is titled "TVT Exact: 21 Editor's Backgrounder (Gynecology). 22 A. Mm-hmm. 23 Q. If you look, do you know what a 24 backgrounder is, Doctor?</p>

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<p>1 A. I do not.</p> <p>2 Q. Are you familiar with the publication</p> <p>3 Gynecology?</p> <p>4 A. No. I don't think that that was the</p> <p>5 publication. I think it's the subject.</p> <p>6 Q. Do you recall what publication this</p> <p>7 appeared in?</p> <p>8 A. Cosmopolitan, Red Book, I think it was a</p> <p>9 consumer magazine, Reader's Digest. I honestly -- I</p> <p>10 vaguely recall that it was a direct-to-consumer thing.</p> <p>11 Q. And do you recall that you were the</p> <p>12 spokesperson within it?</p> <p>13 A. I don't think that I would say that I</p> <p>14 was a spokesperson. I think that I contributed some</p> <p>15 quotes.</p> <p>16 Q. I think it starts off the title is</p> <p>17 "Gynecare TVT Exact: Building on the Legacy of</p> <p>18 Gynecare TVT," and it says, according to Marc Toglia,</p> <p>19 MD, chief of urogynecology for the Main Line Health</p> <p>20 System in suburban Philadelphia, gynecologic surgeons</p> <p>21 now have a new option when retropubic placement of a</p> <p>22 midurethral sling is the treatment of choice in women</p> <p>23 with stress urinary incontinence. Gynecare TVT Exact.</p> <p>24 You see that?</p>	<p>1 Q. And did you write the passage that your</p> <p>2 -- this quote from you right here?</p> <p>3 A. I don't know. It just says that</p> <p>4 Dr. Toglia noted, so I may have had a discussion and an</p> <p>5 interview, and they may have paraphrased me. I</p> <p>6 honestly don't know.</p> <p>7 Q. If you go to the next page at the top,</p> <p>8 Line 1 it says, "Dr. Toglia observed that there has</p> <p>9 been a great deal of concern about synthetic meshes.</p> <p>10 And there's good reason for physicians and patients to</p> <p>11 exercise due diligence when considering a suburethral</p> <p>12 sling to treat SUI."</p> <p>13 Do you agree with that statement?</p> <p>14 A. I was referencing the FDA safety warning</p> <p>15 at the time.</p> <p>16 Q. And, to be fair, that was the FDA safety</p> <p>17 warning of 2008, correct?</p> <p>18 A. I believe so, yes.</p> <p>19 Q. So the FDA safety warning of 2011 hadn't</p> <p>20 come out at that point, right?</p> <p>21 A. Sure. I mean, to be fair, I don't see a</p> <p>22 date, but, you know, I will assume, let's say, for</p> <p>23 argument sake that this was in the same time frame as</p> <p>24 when the product was being launched. That would be my</p>
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<p>1 A. Mm-hmm.</p> <p>2 Q. It goes on, "Gynecare TVT Exact retains</p> <p>3 cardinal features of the Gynecare TVT retropubic</p> <p>4 system, including the laser-cut mesh, protective</p> <p>5 sheath, trocar geometry, and rigid needle design of the</p> <p>6 original Gynecare TVT. TVT Exact is engineered with</p> <p>7 enhancements designed to further reduce tissue and</p> <p>8 organ damage."</p> <p>9 Now, the portion that was already written for</p> <p>10 you, did you write that?</p> <p>11 A. I don't believe so.</p> <p>12 MR. SNELL: Form.</p> <p>13 BY MR. SCHNIEDERS:</p> <p>14 Q. Going on to the next page, about two</p> <p>15 lines down, I guess on Line 3 it says -- is the next</p> <p>16 part that I see that you appear in the article, Doctor.</p> <p>17 It says, Dr. Toglia noted that a good outcome of</p> <p>18 minimally invasive surgery to place suburethral sling,</p> <p>19 whether through the retropubic, transobturator, and I'm</p> <p>20 not even going to get that one. I'll let you read</p> <p>21 this. Why don't you read this.</p> <p>22 A. Well, it's obturator. It's spelled</p> <p>23 wrong or ischiorectal space, begins with the surgeon's</p> <p>24 precision and control.</p>	<p>1 assumption.</p> <p>2 Q. I can show you a little bit more</p> <p>3 specifically.</p> <p>4 A. I think we're saying the same thing.</p> <p>5 Q. I agree.</p> <p>6 A. I don't want to waste anybody's time.</p> <p>7 (Document marked for identification as</p> <p>8 Toglia Deposition Exhibit No. 26.)</p> <p>9 BY MR. SCHNIEDERS:</p> <p>10 Q. Marking this as Exhibit 26. Doctor,</p> <p>11 this is another e-mail from Ms. Peebles. I'm sorry.</p> <p>12 The top of it is an e-mail from Ms. Peebles to someone</p> <p>13 at a group called idanda.com, something like that, and</p> <p>14 it says "OB-GYN backgrounder...I'll give you a call,"</p> <p>15 and then underneath it is an e-mail from you to</p> <p>16 Ms. Peebles.</p> <p>17 A. Okay.</p> <p>18 Q. And it looks like it says, "Rhonda, here</p> <p>19 you go," and it appears that at least part of the quote</p> <p>20 that we just saw in that backgrounder is written right</p> <p>21 there.</p> <p>22 Do you recall if you typed up -- do you recall</p> <p>23 typing up an e-mail and sending it to Rhonda to give</p> <p>24 her a quote?</p>

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<p>1 A. I don't recall it, but I think it speaks</p> <p>2 for itself and, certainly, you know, I'm sort of</p> <p>3 reading through this, and I'm saying to myself, I never</p> <p>4 would have said ischiorectal, we don't use that</p> <p>5 passage, and I obviously read this for factual accuracy</p> <p>6 and I was responding to her and making suggestions.</p> <p>7 Q. And did you notice what you called the</p> <p>8 subject there when you sent it back to her?</p> <p>9 A. TVT ad.</p> <p>10 Q. TVT ad?</p> <p>11 A. TVT ad.</p> <p>12 Q. Is that an advertisement for TVT?</p> <p>13 A. I was probably whatever they were --</p> <p>14 whatever they were referencing it to me.</p> <p>15 Q. Well, I don't -- to be fair, and this is</p> <p>16 how they produced it to us, and we all know how e-mail</p> <p>17 works, it usually says re: or forward or something</p> <p>18 before that if you're just replying. That looks like a</p> <p>19 subject you picked out?</p> <p>20 MR. SNELL: Objection, foundation.</p> <p>21 THE WITNESS: Okay. Again, my</p> <p>22 recollection was there was a short article in</p> <p>23 some consumer journal. It might have been</p> <p>24 Reader's Digest. It might have been</p>	<p>1 it says Gynecare Interceed, and obviously it's talking</p> <p>2 about the barrier product, and then it goes forth, and</p> <p>3 each page has a different product on it. The product</p> <p>4 that I want to call attention to is on Page 9631 are</p> <p>5 the last four numbers of the Bates. It's not perfect,</p> <p>6 but it's better to read than the other pages.</p> <p>7 A. Okay.</p> <p>8 Q. At the top you see it says "Gynecare TVT</p> <p>9 Exact Tension-free Support for Incontinence Roadmap"?</p> <p>10 A. Uh-huh.</p> <p>11 Q. And then it's got several different</p> <p>12 categories on the left-hand side that say Strategy,</p> <p>13 Sales Targeting, Launches, Marketing Tools, Key</p> <p>14 Messages, Awareness, Contracting/Promotions and Prof Ed</p> <p>15 Support.</p> <p>16 Under "Launches" it says Gynecare TVT Exact,</p> <p>17 Gynecare TVT Abbrevio launched May 2010 and</p> <p>18 February 2011 respectively.</p> <p>19 You see that?</p> <p>20 A. Mm-hmm.</p> <p>21 Q. And then under "Marketing Tools" it says</p> <p>22 Gynecare TVT Exact, and it lists marketing tools on the</p> <p>23 right-hand side, Gynecare TVT Exact sales aid, Gynecare</p> <p>24 TVT Exact slim jim, Gynecare TVT Exact procedural</p>
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<p>1 Cosmopolitan, you know. I was glad to see them</p> <p>2 being raising awareness directly to women, you</p> <p>3 know, telling them that there were treatment</p> <p>4 options for stress incontinence.</p> <p>5 BY MR. SCHNIEDERS:</p> <p>6 Q. To be fair, they were only talking about</p> <p>7 their product, right?</p> <p>8 A. I don't know. I mean, I don't know the</p> <p>9 content of the entire article, but I would not -- I</p> <p>10 would suspect that they would just talk about theirs.</p> <p>11 I don't know what the rest of the article entailed.</p> <p>12 Q. It's an ad for TVT?</p> <p>13 A. I don't know that it's an ad for TVT. I</p> <p>14 just referred to it as TVT ad. I don't know why I</p> <p>15 referred to it as TVT ad.</p> <p>16 (Document marked for identification as</p> <p>17 Toggia Deposition Exhibit No. 27.)</p> <p>18 BY MR. SCHNIEDERS:</p> <p>19 Q. I'm going to mark as Exhibit 27 a</p> <p>20 spreadsheet that was given to us. Don't worry about</p> <p>21 the front page. It's extremely hard to read, but we're</p> <p>22 not going there. It's going to be several pages in.</p> <p>23 A. Okay.</p> <p>24 Q. So the first page at the top lots like</p>	<p>1 video, Gynecare TVT Exact procedure steps flash card.</p> <p>2 And then the female patient article featuring</p> <p>3 Dr. Toggia is listed as a marketing tool.</p> <p>4 If you go down to "Awareness," you see that</p> <p>5 scientific meeting presence, and there's several</p> <p>6 different advocacy groups that are all going to be</p> <p>7 presented to, including AUGS, correct?</p> <p>8 MR. SNELL: Objection, foundation,</p> <p>9 advocacy groups.</p> <p>10 THE WITNESS: Yeah, I wouldn't use the</p> <p>11 word advocacy groups. These are professional</p> <p>12 organizations, but I see what they're saying.</p> <p>13 I don't have any involvement in that.</p> <p>14 (Document marked for identification as</p> <p>15 Toggia Deposition Exhibit No. 28.)</p> <p>16 BY MR. SCHNIEDERS:</p> <p>17 Q. I've marked as Exhibit 28 this document,</p> <p>18 it's titled "Overview," and it's got a paragraph at the</p> <p>19 top that says on January 30th, 2012 an approved</p> <p>20 communication (VP of sales & marketing, RBDs, director</p> <p>21 of communication GPD, PD were briefed on this</p> <p>22 communication) went out to approximately 300 surgeons</p> <p>23 who specialize in pelvic surgery (many of whom are</p> <p>24 faculty for EWHU) notifying them of the following.</p>

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<p>1 Bullet point reads, in 2012, we will continue to 2 facilitate these types of important discussions in a 3 variety of formats but will not be holding a one-time, 4 formal summit meeting. Instead, we plan to utilize 5 other interactive mediums and venues that will allow 6 for more frequent and meaningful dialogue with you and 7 your colleagues. 8 There was a very loud and emotional response to 9 this notification, which has provided the EWHU 10 organization the opportunity to re-evaluate how we will 11 need to communicate with this group regarding the FAD 12 mesh situation. 13 See what you've just read there? 14 A. Yes. 15 Q. Do you know what the FAD mesh situation 16 is? 17 A. No. 18 Q. Okay. This is January 30th of 2012 is 19 what it says, and that's just after the FDA had 20 released their bulletin in 2011, correct? 21 A. Mm-hmm. 22 Q. Sorry. I messed up the question, and 23 then you said uh-huh. Was that correct? 24 A. I'm sorry, that is correct. I mean, I</p>	<p>1 Q. And you haven't been provided any 2 documents on that either? 3 MR. SNELL: Objection, misstates earlier 4 testimony. 5 THE WITNESS: I don't have an answer for 6 your question. 7 BY MR. SCHNIEDERS: 8 Q. So if you go down it says, "Key 9 Takeaways," and it's in bold face-to-face "meetings are 10 being requested by the majority of respondents. They 11 want a forum to vent, share & brainstorm on the future. 12 Lack of understanding on the current situation & EWHU's 13 position needs to be clarified." 14 Third bullet point, "A feeling that the company 15 is supporting them needs to be delivered. Interactive 16 meetings have a role but second to face-to-face." 17 Do you recall receiving a communication that 18 would have told you that they were not going to have a 19 summit in 2012? 20 A. Vaguely. 21 Q. If you go to the second page, there's a 22 title that says "Feedback from Surgeons." 23 A. Okay. 24 Q. And then there are numbers and the first</p>
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<p>1 assume that's yes. 2 Q. So it's reasonable to say, although we 3 don't know sitting here, but that probably means the 4 FDA mesh situation, because I don't know what FAD 5 means? 6 A. I don't know that, sir. I don't know 7 that. I can't speak to that. 8 Q. I appreciate that, but we do know that 9 this is, from a temporal standpoint, just after the FDA 10 released its bulletin, correct? 11 MR. SNELL: Form. 12 THE WITNESS: I don't know. All I know 13 is this communicates that a discussion that 14 they were considering not holding another 15 summit. 16 BY MR. SCHNIEDERS: 17 Q. And in 2011 the FDA's release is 18 ultimately what precipitated several products being 19 pulled from the market by Ethicon, correct? 20 MR. SNELL: Lacks foundation. 21 THE WITNESS: I don't know the 22 relationship between the two, in all honesty. 23 I was not part of that decision. 24 BY MR. SCHNIEDERS:</p>	<p>1 one is Bob Shull. 2 Do you know Bob Shull? 3 A. I do, yes. 4 Q. Second one is Doug Grier. 5 Do you know Doug Grier? 6 A. I do not, no. 7 Q. And Mike Vardy, then Neena Agarwala and 8 then there you are, Doctor, Marc R. Toggia, M.D., 9 Number 5. 10 Do you see that? 11 A. Yes. 12 Q. And what you've written here is, "Given 13 the current controversies and challenges that we 14 physician are facing with regards to the use of vaginal 15 mesh, I would like to argue that we need this type of 16 meeting now more than ever. The future for vaginal 17 mesh seems somewhat uncertain, however, many of us 18 still believe that it serves a vital, albeit more 19 limited role." 20 Continues on, "Ethicon's role in providing 21 peer-to-peer support with regards to new and innovative 22 products is what has separated your company from the 23 rest of the field. Ethicon's willingness to partner 24 with and support surgeons in this regard has been</p>

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<p>1 second to none.</p> <p>2 I would ask you to reconsider this decision.</p> <p>3 If cost and travel are a major deterrent, I might</p> <p>4 suggest that you consider a lower cost venue, such as</p> <p>5 Philadelphia, or returning to Florida. I am sure that</p> <p>6 many of us would be willing to sacrifice the bells and</p> <p>7 whistles to simply get together and meet again."</p> <p>8 Did I read that correctly?</p> <p>9 A. Yes.</p> <p>10 Q. Going back to the first page statement,</p> <p>11 you wrote, "The future for vaginal mesh seems somewhat</p> <p>12 uncertain, however, many of us still believe that it</p> <p>13 serves a vital, albeit more limited role."</p> <p>14 What did you mean by "a vital, albeit more</p> <p>15 limited role"?</p> <p>16 A. Well, you know, obviously the FDA's</p> <p>17 statement was going to be interpreted differently by</p> <p>18 many people, including people of your profession, sir,</p> <p>19 and obviously this was going to create challenges</p> <p>20 really in how we speak to people, you know, patients,</p> <p>21 women, women that had it implanted previously, people</p> <p>22 that were currently planning on implanting it.</p> <p>23 At the time I don't believe that I was aware of</p> <p>24 any plans to pull the product. The FDA warning --</p>	<p>1 a little bit out of sync.</p> <p>2 And, you know, again, Ethicon is based in New</p> <p>3 Brunswick, New Jersey, which is a stone's throw from</p> <p>4 Philadelphia. I was just saying to them, look, let's</p> <p>5 still have this meeting, it could be a quick meeting.</p> <p>6 You know, let's just get the usual group together,</p> <p>7 wherever it might be convenient. Again, most of the</p> <p>8 users, my understanding, were East Coast users. That's</p> <p>9 why I said Philly or Florida.</p> <p>10 Now, I'm sorry, and I apologize, I realize I'm</p> <p>11 off track. So, yes, as the science has supported,</p> <p>12 anterior Prolift works extremely well in the anterior</p> <p>13 vaginal compartment, and the literature states quite</p> <p>14 clearly that the anatomic results are superior compared</p> <p>15 to native tissue repair.</p> <p>16 Prolift in the posterior compartment, that data</p> <p>17 was not as robust, and so when I said limited -- vital</p> <p>18 but limited role, vital meaning the most common</p> <p>19 problem, the one that causes women the most symptoms is</p> <p>20 anterior prolapse, and the data and experience clearly</p> <p>21 demonstrate that this is a safe and effective</p> <p>22 technique.</p> <p>23 So the question in my mind was is that what we</p> <p>24 concentrate on, do we concentrate on anterior Prolift</p>
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<p>1 yeah, the FDA warning also -- I mean, most of us</p> <p>2 involved at this level were not aware of the numbers of</p> <p>3 complications that had been reported to the FDA. I</p> <p>4 think we were surprised because, according to the</p> <p>5 literature that we were reading and our own experience,</p> <p>6 we were not seeing that complications but also the FDA</p> <p>7 was not very clear. The distinction -- their initial</p> <p>8 statement seemed to sort of blend stress incontinence</p> <p>9 with prolapse repair, whereas many of us thought that</p> <p>10 they were referring specifically to prolapse repair.</p> <p>11 And so in the past, the summit meeting was an</p> <p>12 opportunity to bring people together and foster</p> <p>13 discussions, and I was pointing out to them that, you</p> <p>14 know, in that regard, it was still very variable to</p> <p>15 bring us all together so that we could discuss, you</p> <p>16 know, how are we going to counsel patients moving</p> <p>17 forward, how do we counsel patients that have been</p> <p>18 implanted and are doing well but have concerns. You</p> <p>19 know, immediately people were saying that there was a</p> <p>20 recall, when, in fact, there wasn't a recall.</p> <p>21 Again, most of us were reading the literature,</p> <p>22 literature supported that this was a safe procedure</p> <p>23 with excellent safety and efficacy. Our own experience</p> <p>24 would support that, mirror that as well. So it seemed</p>	<p>1 as opposed to posterior Prolift. Certainly, those of</p> <p>2 us that were looking at things from a pooled analysis</p> <p>3 were reaching the conclusion that the posterior</p> <p>4 compartment, dyspareunia was a problem with all the</p> <p>5 repairs. It wasn't clear to us -- it seemed to us that</p> <p>6 it was similar between the two, although we were</p> <p>7 getting these reports. So I was just advocating that,</p> <p>8 and I think it's supported by my report, that at the</p> <p>9 apex and anteriorly, this was a safe and effective</p> <p>10 technique in the product, and that's what I meant by</p> <p>11 vital because that's the most common, the most</p> <p>12 bothersome, limited, let's concentrate on the anterior</p> <p>13 and the apex.</p> <p>14 Q. What did you mean by "Ethicon's</p> <p>15 willingness to partner with and support surgeons"?</p> <p>16 A. Again, many of us felt there was great</p> <p>17 value in these summit meetings. I recall that at one</p> <p>18 or more of these meetings, some of the key inventors of</p> <p>19 both the TVT and the TVM were brought in from Europe,</p> <p>20 and we were allowed to listen to them discuss the</p> <p>21 development of the product. We were able to ask them</p> <p>22 very clinical questions. So I remember asking one of</p> <p>23 the TVT individuals who had published on it what do you</p> <p>24 tell patients when they can return to work and exercise</p>

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<p>1 and stuff like that. So we found the summit to be 2 invaluable as an opportunity for colleagues to get 3 together to further discuss the topic and specifically 4 to listen to experts both nationally and 5 internationally. 6 Q. But you would agree that it was an 7 uncertain time for mesh, correct? 8 MR. SNELL: Object, form. 9 THE WITNESS: I would not agree. I 10 think at the time I think the FDA's mesh 11 message, excuse me, was uncertain because, 12 again, initially they didn't draw -- they 13 didn't -- they said -- I'm sorry. I lost my 14 train of thought. 15 BY MR. SCHNIEDERS: 16 Q. The uncertainty you were referring to 17 was what the FDA's position was; is that what you're 18 telling me? 19 A. It was unclear whether the additional 20 cases reported were sling related cases versus vaginal 21 mesh related cases, as well as what products were 22 involved. 23 (Document marked for identification as 24 Toggia Deposition Exhibit No. 29.)</p>	<p>1 Q. You see on the bottom right-hand corner, 2 it's got Ethicon Women's Health & Urology logo, right? 3 A. Yes. 4 Q. We can go off the record, and you can 5 look over that for a second, if you'd like to, Doctor. 6 MR. SCHNIEDERS: Let's go off the record 7 so he can look at the PowerPoint. 8 (Brief recess taken at 6:33 p.m.) 9 (Deposition resumes at 6:34 p.m.) 10 BY MR. SCHNIEDERS: 11 Q. Doctor, I think you were saying that you 12 may have worked on this, you're just not sure, right? 13 A. I don't recognize this. 14 Q. Okay. But suffice it to say, it's got a 15 Bates number, it was produced to us, and it's titled 16 "The Mesh Story," and it's got your name on it, right? 17 A. Correct. 18 Q. It could possibly be one of those slide 19 decks that was made by Ethicon for a presentation they 20 wanted you to give? 21 A. I would suspect so, yes. 22 Q. Okay. And, typically, when you would 23 give PowerPoints on behalf of Ethicon, would you do so 24 with Ethicon's logo on it?</p>
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<p>1 BY MR. SCHNIEDERS: 2 Q. Marking as Exhibit 29 a PowerPoint. 3 Doctor, do you recall this PowerPoint? 4 A. I don't know if I ever gave this power 5 point in a meeting or not. 6 Q. On the second page of the document you 7 see it's titled "The Mesh Story." 8 Do you see that? 9 A. Yes. 10 Q. And it's got your name on it as Director 11 of Urogynecology, Main Line Health System, 12 Philadelphia, PA right? 13 A. Yes. 14 Q. Are you familiar with The Mesh Story, 15 was that verbiage you ever used? 16 A. No. 17 MR. SNELL: Do you have a date on this 18 document? 19 MR. SCHNIEDERS: What's that? 20 MR. SNELL: Do you have a date for this? 21 MR. SCHNIEDERS: I didn't look, to be 22 honest. 23 MR. SNELL: That's okay. 24 BY MR. SCHNIEDERS:</p>	<p>1 A. Typically, I am presenting material 2 prepared by Ethicon in compliance with the FDA 3 regulations, and I would disclose at the beginning that 4 I was up there to speak on behalf of the company to 5 present the company slides. 6 Q. Okay. And so if you go to the second 7 page, it says "Content." 8 A. Yes. 9 Q. And it gives a few things about -- and 10 the context, even though it's not dated, and, frankly, 11 it was my fault for not looking at the Bates number and 12 custodian, but the context would tell us that this has 13 got to be after a recent FDA notice, I suspect; is that 14 fair? 15 A. I think so. I'm -- I would think that 16 this is after the October 2008. 17 Q. So you see the content there it says, 18 "What does the FDA notice tell us?" And then "Why is 19 our mesh different?" And is that how you talk in 20 PowerPoints that you give on behalf of Ethicon -- 21 A. No. 22 Q. -- you say our mesh? 23 A. No, I have no ownership. I have no 24 ownership. That would be an example of something that</p>

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<p>1 I might strike through and say, you know, you need to</p> <p>2 be specific that this is Ethicon.</p> <p>3 Q. And it says, "How does it work? Why is</p> <p>4 it designed this way? What does that mean</p> <p>5 physiologically?"</p> <p>6 A. Yes.</p> <p>7 Q. Going on to the next page it says</p> <p>8 "Navigating the Mesh Maze."</p> <p>9 Did you ever call it the mesh maze?</p> <p>10 A. No.</p> <p>11 Q. Bullet point it says, "We have to deal</p> <p>12 with competing messages surrounding mesh."</p> <p>13 Do you agree with that statement?</p> <p>14 A. I don't know what that means. I read</p> <p>15 that as conflicting, but I don't know what that means.</p> <p>16 Q. Okay. And it says, "Goal is safe and</p> <p>17 effective treatment for patients with SUL."</p> <p>18 A. Yes.</p> <p>19 Q. And it says, "FDA has issued a Public</p> <p>20 Health Notification warning about risks of mesh."</p> <p>21 A. Yes.</p> <p>22 Q. "Patients are concerned about mesh</p> <p>23 implant. We have to help our customers to understand</p> <p>24 how to minimize their risk."</p>	<p>1 A. As a surgeon, I look at this as we need</p> <p>2 to talk about women and help women to understand and --</p> <p>3 I mean, I'm really lost. I'm so sorry. I have no</p> <p>4 idea.</p> <p>5 Q. Does it make you mad that Ethicon put</p> <p>6 your name on something like this?</p> <p>7 A. No. I mean, I don't -- again, this may</p> <p>8 have been an idea that they floated by me. I don't</p> <p>9 know.</p> <p>10 Q. So the next slide goes on and talks</p> <p>11 about the FDA alert, October of 2008.</p> <p>12 And then the next slide basically breaks down</p> <p>13 what that alert said, FDA Recommendations, be vigilant</p> <p>14 for potential adverse events (erosion, infection).</p> <p>15 Watch for perforation from tools. Inform patients that</p> <p>16 mesh implantation is permanent and that some</p> <p>17 complications may require additional surgery that may</p> <p>18 or may not correct the complication. Inform patients</p> <p>19 about potential for serious complications affecting</p> <p>20 QOL, quality of life (dyspareunia, scarring). Provide</p> <p>21 patient with a written copy of the patient labeling.</p> <p>22 Do you provide your patients with written</p> <p>23 copies of the patient labeling?</p> <p>24 A. I think that -- again, I think what</p>
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<p>1 It says our customers right there. Do you</p> <p>2 recall from the document we saw before that physicians</p> <p>3 are referred to internally as customers?</p> <p>4 A. Yeah, I don't know that that's what this</p> <p>5 refers to. Again, I'm quite certain this is not</p> <p>6 something that I ever presented myself because I would</p> <p>7 not -- I would never have used the term customer in any</p> <p>8 form. I not have used the our on the previous page. I</p> <p>9 would not have used our customers.</p> <p>10 This may have been an outline or a markup of</p> <p>11 something that they were thinking about. I can't tell</p> <p>12 you I ever saw this. I have no recollection of seeing</p> <p>13 this. This is certainly not something I've presented.</p> <p>14 Q. But fair to say that it says we have to</p> <p>15 help our customers to understand how to minimize their</p> <p>16 risk. Fair reading of that is that Ethicon is trying</p> <p>17 to help doctors that use their products to minimize</p> <p>18 their risk, right?</p> <p>19 MR. SNELL: Foundation.</p> <p>20 THE WITNESS: I don't agree, no.</p> <p>21 BY MR. SCHNIEDERS:</p> <p>22 Q. What do you think it means?</p> <p>23 A. I don't know the context, sir.</p> <p>24 Q. Okay. Well, that's fair.</p>	<p>1 they've done here is they have provided a summary of</p> <p>2 what the FDA had written. In our practice, we do have</p> <p>3 readily available each of the FDA safety warnings. We</p> <p>4 have the position statements from our organization. We</p> <p>5 have brochures from Ethicon on the TVT, which would</p> <p>6 include the labeling information. So those are</p> <p>7 discussed and, when appropriate, offered to the</p> <p>8 patient.</p> <p>9 Q. If you go to the next page it says, "We</p> <p>10 should be counseling patients differently about mesh.</p> <p>11 When selecting a sling 'what's left behind' matters</p> <p>12 more than the delivery system."</p> <p>13 What does that mean to you, Doctor?</p> <p>14 A. To me what this means, and I think</p> <p>15 you'll get your answer towards the end of this</p> <p>16 presentation, is that the majority of the science</p> <p>17 demonstrating the safety and efficacy of the TVT</p> <p>18 product is specifically based upon the TVT product.</p> <p>19 However, other companies that have similar products are</p> <p>20 sort of borrowing from research that was done on TVT,</p> <p>21 and so I think what we were speaking to here is the</p> <p>22 fact that we have a wealth of data on TVT specifically.</p> <p>23 And so when we talk to people about sling</p> <p>24 choices, and, remember, there are 49 slings on the</p>

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<p style="text-align: right;">Page 242</p> <p>1 market or were on the market, what do we tell people, 2 what do we tell, do we tell them we're going to do a 3 sling, we're going to do a synthetic sling, we're 4 specifically using one versus another. 5 You know, this was -- the use of implants -- 6 we've used implants from the '50s, but it was becoming 7 more commonplace. So as a surgeon, our process for 8 informed consent and discussion was evolving. We all 9 had different methods. When we would go to the summit 10 meeting, different people would say, this is how I 11 present the information, this is how I present the 12 information, this is what I tell the patient, and I 13 think that that's probably what they were -- I think 14 that they were specifically saying, look, we have the 15 data, we've got -- at the time we have 40 some odd 16 clinical trials specifically with our product, whereas 17 competitors may have less than ten products. 18 Q. And here it says "meshes are different 19 and should be assessed by their own clinical outcomes," 20 which fits in with what you're saying right now, right? 21 A. Mm-hmm. 22 Q. And then the fourth category there it 23 says, "In a category of slings where 'Level I Evidence' 24 exists with proven safety and efficacy, why accept a</p>	<p style="text-align: right;">Page 244</p> <p>1 BY MR. SCHNIEDERS: 2 Q. Do you believe that AMS or Boston 3 Scientific or Bard's mesh can cause complications? 4 A. I don't, no, based upon my extensive 5 review of the literature and the report that I've 6 presented previously. It's not the material. 7 Q. It goes on it says, "What are the 8 mechanical properties of an ideal sling design?" And 9 it's got four bullet points and tell me if you agree 10 with these, that it "incorporates into tissue." 11 Do you agree? 12 A. Sorry. I lost my place. 13 Q. It's right after the pictures of the 14 mesh. It's titled "What are the mechanical properties 15 of an ideal sling design?" 16 Do you see it, Doctor? 17 A. I do. I mean, I believe that these are 18 points for discussion. So, you know, is it important, 19 you know, how a sling incorporates into the tissue, is 20 it important the stiffness, is there a relationship 21 between stiff and non-stiff? These are all the things 22 that we were exploring. 23 Obviously, we were all comfortable that the 24 introduction of midurethral slings was a major advance</p>
<p style="text-align: right;">Page 243</p> <p>1 mesh without outcomes data?" 2 Level I evidence is something that you say 3 quite a bit, right? 4 A. Yes. 5 Q. And the next page, "All meshes are not 6 equal." And then it goes on to show the pictures of 7 the different meshes, "All are polypropylene...but 8 meshes have differences." 9 Do you recall this slide? 10 A. I mean, this slide has come and gone 11 throughout the history of these discussions as far as 12 specifically how these products are knitted. 13 Q. And do you believe that AMS or Boston 14 Scientific or Bard's mesh is different than Ethicon's? 15 MR. SNELL: Form. 16 THE WITNESS: I don't have much 17 experience using those products. Again -- I 18 just, again, I'm an evidence-based guy, and you 19 can see just clinically my entire experience, I 20 stick with what seems to have the most 21 evidence, so they're all polypropylene, they 22 all are Type I Amid meshes, macroporous. You 23 know, I'm not aware of major differences 24 between them.</p>	<p style="text-align: right;">Page 245</p> <p>1 in this field. We were aware of what was being 2 reported to the FDA, so we were saying to ourselves, 3 okay, we're on the front line, let's dig into this. I 4 can't tell you that we drew any direct conclusions, but 5 these were the questions that we were asking. 6 Q. But, sitting here today, you can't point 7 to those four things as the properties of an ideal 8 sling design? 9 A. I'm sorry, I mean, yes. Obviously, it 10 is important how the sling incorporates itself into 11 tissue. You know, to me it just speaks to 12 biotolerability, and, yes, that's important as well. 13 Remember that around this period of time there were a 14 couple slings, ObTape, that was taken off the market, 15 had a very, very different design. The original 16 Protogen sling, which is the precursor, was taken off 17 the market. I vaguely remember that somebody had a 18 silicone-coated sling that was not used, you know, 19 after a while. So, again, obviously, these type of 20 things facilitate discussion. 21 Q. If you go two more slides down, it says, 22 "Gynecare TVT Tension-free Support for Incontinence 23 Mesh: Unique Properties." It says, "Measurable 24 differences from other polypropylene meshes, largest</p>

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<p>1 pore size, lowest stiffness, highest elongation." 2 Are those important to you as a physician? 3 A. Again, I did not write this information, 4 you know, what we considered to be important clinically 5 and what the literature supports is that we're using a 6 macroporous product. I mean, is there a difference 7 between 1,100 and 1,300 clinically? I don't believe 8 so. Is there a significance to stiffness? I don't 9 know. Elongation, I don't know either. Is it true 10 that the TVT mesh has the largest pore size? Yes. 11 That it has the lowest stiffness? You know, my 12 recollection, yes. I think those statements are 13 supported by the title. I don't think it speaks to any 14 kind of clinical. 15 Q. Significance? 16 A. Application, clinical significance, 17 clinical difference. 18 Q. Can you go back two pages to the page 19 that looks like the chart like this? 20 A. Right. 21 Q. You see there under the asterisk at the 22 bottom it says, AMS mesh was tested without tensioning 23 suture. In another study comparison when measured with 24 the tensioning suture SPARC has a stiffness of</p>	<p>1 "Prolene polypropylene mesh is highly inert." 2 You see that page, Doctor? 3 A. Mm-hmm. 4 Q. And then it says, "treated over 5 1.5 million patients," and then it says "longest term 6 follow-up of any mesh at 11.5 years," and "The most 7 'Level I Evidence' with 41 RCTs." Now, that bottom 8 cite, Number 7, if you go over to the references, it 9 says there was a PubMed search, and you can see PubMed 10 search was from 1/26 of '09 through 2/20 of '09, which 11 gives us a time frame for when this would have 12 occurred. I'm assuming you didn't run that PubMed 13 search, right? 14 A. That is correct. 15 MR. SCHNIEDERS: Let me take five. 16 (Brief recess taken at 6:51 p.m.) 17 (Deposition resumes at 6:57 p.m.) 18 (Document marked for identification as 19 Toggia Deposition Exhibit No. 30.) 20 BY MR. SCHNIEDERS: 21 Q. I have just marked as Exhibit 30 a 22 ProPublica document or it comes from the ProPublica 23 database where you can type in doctors' names and it 24 shows some of the payments they've received from the</p>
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<p>1 .53 nanograms per milliliter and Gynecare TVT 2 Tension-free Support for Incontinence has a stiffness 3 of .23 nanograms per milliliter. This is a highly 4 significant difference, and it gives a P value there. 5 You see that? 6 A. Yes. 7 Q. So, apparently, it wasn't you, but 8 whoever put this PowerPoint together and put your name 9 on it felt that that was an important difference, 10 right? 11 A. Well, you know, yes. I mean, there's -- 12 but there's a difference between clinically significant 13 and the fact that -- I mean, that the numbers are 14 highly significant difference. As we go through this, 15 as we had -- as you brought up earlier this afternoon, 16 there was a document that suggested that I participated 17 in a luncheon discussion at a meeting. It may be that 18 this was something that was being considered for that 19 venue. I don't know. I have no recollection that this 20 is actually what I presented, but perhaps there's a 21 relation -- we don't have a date for this. 22 Q. Finishing up, there's a page that is 23 right before what I've called the footnotes or the 24 credits I guess at the end, it's titled -- it says</p>	<p>1 past couple of years. 2 Are you familiar with this type of document? 3 A. I am, I am. 4 Q. If you go to the second page, they don't 5 print out very nicely every time, but on the second 6 page it states that from August of 2013 through 7 December of 2014, you received a total of 137 payments 8 for 45,967 -- \$45,976. 9 Does that sound about right to you or sound 10 high, sound low? 11 A. And, again, not wanting to be 12 argumentative, I take issue with the 137 payments. I 13 think that if somebody brought lunch to my office or to 14 my office staff, that perhaps that might be counted as 15 a payment. 16 Q. I think, in fact, it is. If you look 17 under down here under types of payments, it's going to 18 tell you exactly what it was. 19 A. Right. I think also I do recall, and it 20 may not be specifically this time period, that Pfizer 21 had floated a study by me. We submitted the 22 information to the Lankenau Institute of Medical 23 Research. They paid that institute \$2,000 for their 24 review of the protocol. We would not participate, but</p>

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<p>1 it was reported as income to me, but I never saw that</p> <p>2 income.</p> <p>3 Q. So I'm going to ask you -- it lists</p> <p>4 through every single payment here and talks it through.</p> <p>5 A. Sure.</p> <p>6 Q. I'm not going to ask you about each</p> <p>7 individual payment.</p> <p>8 A. Sure.</p> <p>9 Q. I want to highlight or mention the</p> <p>10 company that's listed just to see if that's something</p> <p>11 that sounds right, like you would have received</p> <p>12 something from that company?</p> <p>13 A. I mean, I see stuff on here that I</p> <p>14 clearly had no involvement with, but go ahead.</p> <p>15 Q. That's fine, just tell me as we go</p> <p>16 along.</p> <p>17 A. Sure.</p> <p>18 MR. SNELL: Note my continuing objection</p> <p>19 as to the foundation, accuracy of this</p> <p>20 document, and move motion in limine to preclude</p> <p>21 this document.</p> <p>22 Go ahead.</p> <p>23 BY MR. SCHNIEDERS:</p> <p>24 Q. Astellas Pharma US, I think we talked</p>	<p>1 Number 14, and it's the top one.</p> <p>2 A. I'm sorry. And this was which year?</p> <p>3 Q. March 25th of 2014.</p> <p>4 A. Got you. I mean, there's probably</p> <p>5 another physician in my office. At that time there</p> <p>6 were two other physicians in my practice, and they</p> <p>7 might have been talking to them about either the</p> <p>8 morcellator product, that wouldn't be me. That's not</p> <p>9 something that I would have likely participated in.</p> <p>10 Q. And I would note that and consistent</p> <p>11 with what you said earlier that Astellas seems to be</p> <p>12 the name that comes up the most often.</p> <p>13 Does that sound right to you?</p> <p>14 A. Yes, during this time period, probably</p> <p>15 the work that I did was with overactive bladder having</p> <p>16 participated in some of the research previously.</p> <p>17 Q. Looks like there was food related to a</p> <p>18 drug called Toviaz from Pfizer.</p> <p>19 Do you recall that?</p> <p>20 A. Yeah, that's food provided to my office</p> <p>21 staff. I may or may not have been there.</p> <p>22 Q. Same thing with regard to Warner</p> <p>23 Chilcott for a drug called Enablex?</p> <p>24 A. Yes.</p>
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<p>1 about them earlier; is that right?</p> <p>2 A. Yes.</p> <p>3 Q. AMS?</p> <p>4 A. I'm sorry. The question is specifically</p> <p>5 is did I?</p> <p>6 Q. Do you recall consulting for American</p> <p>7 Medical Systems Inc.?</p> <p>8 A. Yes. Some of them, for example, Elevate</p> <p>9 is AMS. I never consulted. That is not a consulting</p> <p>10 thing, \$19. That was maybe a lunch, I don't know. I</p> <p>11 honestly don't know.</p> <p>12 Q. Uroplasty, Inc. do you recall that?</p> <p>13 A. Yes.</p> <p>14 Q. Is Uroplasty, Inc. a device</p> <p>15 manufacturer?</p> <p>16 A. Uroplasty was a device manufacturer.</p> <p>17 They were renamed Cogentix, C-o-g-e-n-t-i-x, and I</p> <p>18 consulted with them on productional education slide</p> <p>19 development.</p> <p>20 Q. There were a handful of Ethicon on here.</p> <p>21 There's one on March 25th of 2014, which is Page 14 of</p> <p>22 44 at the top. It says uterine surgery for \$107?</p> <p>23 A. I'm sorry, where?</p> <p>24 Q. If you go to the numbering up here,</p>	<p>1 Q. Noven Pharmaceuticals for a drug called</p> <p>2 Brisdelle?</p> <p>3 A. That's not me. Brisdelle I believe is a</p> <p>4 birth control pill. That's not accurate. I never sat</p> <p>5 in on a lunch for -- no, I'm sorry, Brisdelle, PMS</p> <p>6 treatment perhaps. Again, probably marketed towards my</p> <p>7 junior partner. Forteo, not me.</p> <p>8 Q. Forteo?</p> <p>9 A. No, not me. I have no idea what</p> <p>10 Xartemis is, never heard of that.</p> <p>11 Q. Is that the one that's Mallinckrodt?</p> <p>12 A. I have no idea.</p> <p>13 Adhesion prevention, I don't recognize that at</p> <p>14 all.</p> <p>15 Q. Allergen for Botox?</p> <p>16 A. I've never used Botox. I don't believe</p> <p>17 that would be myself either. This is not that</p> <p>18 accurate.</p> <p>19 Q. Just so you're aware, for your own sake,</p> <p>20 you can go and contest anything that's not accurate.</p> <p>21 A. I appreciate that. Thank you. Yes.</p> <p>22 Q. If you do feel that way.</p> <p>23 That's the majority of the companies there.</p> <p>24 Lastly, Doctor, when you give a risk-benefit</p>

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<p>1 discussion to any of your female patients about the</p> <p>2 potential of receiving a TVT device or receiving</p> <p>3 Gynemesh PS, do you disclose to them that you had a</p> <p>4 financial relationship with Ethicon?</p> <p>5 A. I do.</p> <p>6 Q. And what do you tell them?</p> <p>7 A. I tell them that I have been involved</p> <p>8 with professional education, research study, that I've</p> <p>9 consulted on designs, development of such products. I</p> <p>10 disclose as much as, you know, they're interested in</p> <p>11 hearing.</p> <p>12 Q. No amounts, I assume, right?</p> <p>13 A. I don't tell them specific amounts.</p> <p>14 Obviously, these are all public records. You can find</p> <p>15 out how much Medicare paid me last month if you wanted</p> <p>16 to.</p> <p>17 MR. SCHNIEDERS: Doctor, I think my time</p> <p>18 is up. I have no further questions. Thank you</p> <p>19 for your time.</p> <p>20 BY MR. SNELL:</p> <p>21 Q. Doctor, I'm just going to ask a few</p> <p>22 follow-up questions on a couple topics.</p> <p>23 Doctor, I'll represent to you that depositions</p> <p>24 of the plaintiffs' experts are ongoing. I know you've</p>	<p>1 are there company documents and things of that nature</p> <p>2 as well?</p> <p>3 MR. SCHNIEDERS: Object to the form.</p> <p>4 THE WITNESS: I mean, obviously, the</p> <p>5 Prolift documents, these are slides on Prolift,</p> <p>6 so, yes. There are various e-mails.</p> <p>7 BY MR. SNELL:</p> <p>8 Q. You were asked about your expertise in</p> <p>9 various areas. Let me ask you about that.</p> <p>10 Do you believe you're an expert in how the</p> <p>11 chemical polypropylene the polymer performs in pelvic</p> <p>12 surgery in a woman?</p> <p>13 MR. SCHNIEDERS: Object to form.</p> <p>14 THE WITNESS: Yes, I do believe I'm an</p> <p>15 expert in that.</p> <p>16 BY MR. SCHNIEDERS:</p> <p>17 Q. Besides, obviously, your testimony that</p> <p>18 you've utilized polypropylene over many decades before</p> <p>19 pelvic surgery, have you also researched that topic in</p> <p>20 the reliable scientific medical literature?</p> <p>21 MR. SCHNIEDERS: Object to the form.</p> <p>22 THE WITNESS: Yes, I have.</p> <p>23 BY MR. SNELL:</p> <p>24 Q. Have you analyzed the design of the</p>
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<p>1 been provided Dr. Ostergard's deposition, but there are</p> <p>2 many other depositions going on, and it will be, I'll</p> <p>3 represent, sent to you.</p> <p>4 Could you plan to reserve the right to issue</p> <p>5 any new or updated opinions based on depositions of the</p> <p>6 plaintiffs' experts?</p> <p>7 MR. SCHNIEDERS: Object to the form.</p> <p>8 THE WITNESS: Yes, I would say that</p> <p>9 sounds fair.</p> <p>10 BY MR. SNELL:</p> <p>11 Q. And will you look at any new studies</p> <p>12 that come out that you may or may not find to be</p> <p>13 pertinent to your opinions?</p> <p>14 MR. SCHNIEDERS: Object to the form.</p> <p>15 THE WITNESS: Yes, I read this</p> <p>16 literature frequently so...</p> <p>17 BY MR. SNELL:</p> <p>18 Q. You were asked questions about if you</p> <p>19 were provided company documents. Besides the IFUs, the</p> <p>20 professional education materials, the slide decks, the</p> <p>21 videos and all the stuff that are on the thumb drive</p> <p>22 somewhere that we're going to put in the box as</p> <p>23 Exhibit 4, I just want to call to your attention. So</p> <p>24 in Dr. Ostergard's materials that were provided to you,</p>	<p>1 devices that utilize the Ethicon polypropylene?</p> <p>2 MR. SCHNIEDERS: Object to the form.</p> <p>3 THE WITNESS: Yes, I have.</p> <p>4 BY MR. SNELL:</p> <p>5 Q. You were asked if you're an expert in</p> <p>6 polymer chemistry. Do you believe you're an expert in</p> <p>7 that field?</p> <p>8 MR. SCHNIEDERS: Object to the form.</p> <p>9 THE WITNESS: As it pertains to what</p> <p>10 we're discussing here and its intended use,</p> <p>11 yes, I am.</p> <p>12 BY MR. SNELL:</p> <p>13 Q. And before you even went to medical</p> <p>14 school, I think you testified you have a degree in</p> <p>15 biochemistry as well?</p> <p>16 A. Correct.</p> <p>17 Q. Do you believe you have a very good</p> <p>18 working knowledge and understanding of chemistry?</p> <p>19 A. Yes, I have.</p> <p>20 Q. Including the chemistry of polypropylene</p> <p>21 and what -- the atoms or molecules it's made up of?</p> <p>22 A. That's correct. I did research as an</p> <p>23 undergraduate in silastic plastic delivery systems.</p> <p>24 Q. You talked some in this deposition about</p>

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<p>1 your consulting and evaluation of the development and</p> <p>2 design of sling and prolapse devices.</p> <p>3 In your earlier deposition, you recall covering</p> <p>4 that subject as well?</p> <p>5 A. I do, yes.</p> <p>6 Q. Do you stand by your testimony from your</p> <p>7 earlier deposition in the Mullens case about the</p> <p>8 various design and development work you did?</p> <p>9 MR. SCHNIEDERS: Object to the form.</p> <p>10 THE WITNESS: Yes, I believe we covered</p> <p>11 that pretty extensively.</p> <p>12 BY MR. SNELL:</p> <p>13 Q. Do you recollect in that testimony you</p> <p>14 discussed that you were involved in the design</p> <p>15 validation of the Gynemesh M mesh?</p> <p>16 MR. SCHNIEDERS: Object to the form.</p> <p>17 THE WITNESS: Yes.</p> <p>18 BY MR. SNELL:</p> <p>19 Q. And is that a prolapse mesh similar to</p> <p>20 Gynemesh PS?</p> <p>21 MR. SCHNIEDERS: Object to the form.</p> <p>22 THE WITNESS: Yes.</p> <p>23 BY MR. SNELL:</p> <p>24 Q. Do you recollect testifying and telling</p>	<p>1 have consulted and evaluated the design of other</p> <p>2 Ethicon pelvic floor products over various time</p> <p>3 periods?</p> <p>4 MR. SCHNIEDERS: Object to the form.</p> <p>5 THE WITNESS: Yes, I have.</p> <p>6 BY MR. SNELL:</p> <p>7 Q. For example, you testified about your</p> <p>8 design evaluation and your work with the TVT Exact</p> <p>9 product for stress urinary incontinence?</p> <p>10 MR. SCHNIEDERS: Object to the form.</p> <p>11 THE WITNESS: Yes, starting from the</p> <p>12 concept of the design all the way through the</p> <p>13 engineering, all the way through the</p> <p>14 suitability of the product and the professional</p> <p>15 education component of that, which included the</p> <p>16 teaching, the filming of the video</p> <p>17 demonstrating the technique.</p> <p>18 BY MR. SNELL:</p> <p>19 Q. And would that professional education</p> <p>20 also include the instructions for use?</p> <p>21 MR. SCHNIEDERS: Object to the form.</p> <p>22 THE WITNESS: Yes, it did include the</p> <p>23 instructions for use.</p> <p>24 BY MR. SNELL:</p>
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<p>1 the lawyers under oath that in your role as being one</p> <p>2 of the design validation surgeons, you assessed the</p> <p>3 suitability, safety, efficacy and adequacy of the</p> <p>4 design of that product?</p> <p>5 MR. SCHNIEDERS: Object to the form.</p> <p>6 THE WITNESS: I did, yes.</p> <p>7 BY MR. SNELL:</p> <p>8 Q. Do you also recall and recollect your</p> <p>9 testimony that in the design validation activities you</p> <p>10 performed on the prolapse mesh for Ethicon, you also</p> <p>11 assessed the instructions for use as to its adequacy</p> <p>12 and clarity and how it laid out instructions?</p> <p>13 MR. SCHNIEDERS: Object to the form.</p> <p>14 THE WITNESS: Yes, I did.</p> <p>15 BY MR. SNELL:</p> <p>16 Q. Do you recollect that you testified that</p> <p>17 in connection with your evaluation of the IFU for the</p> <p>18 prolapse device, you were asked whether it was clear or</p> <p>19 cohesive or accurate?</p> <p>20 MR. SCHNIEDERS: Object to the form.</p> <p>21 THE WITNESS: Yes, I did.</p> <p>22 BY MR. SNELL:</p> <p>23 Q. And besides the prolapse mesh, I think</p> <p>24 you testified here today and you testified earlier, you</p>	<p>1 Q. And so do you believe you're an expert</p> <p>2 and qualified to opine on the adequacy of the</p> <p>3 instructions for use for the Gynemesh PS and Prolift</p> <p>4 and the TVT product?</p> <p>5 MR. SCHNIEDERS: Object to the form.</p> <p>6 THE WITNESS: Yes, I will agree with</p> <p>7 that.</p> <p>8 BY MR. SNELL:</p> <p>9 Q. And did you actually teach the IFU</p> <p>10 during your professional education activities for</p> <p>11 various products in addition to the discussions or I</p> <p>12 think you called them proctorships as well?</p> <p>13 MR. SCHNIEDERS: Object to the form.</p> <p>14 THE WITNESS: Yes, I did.</p> <p>15 BY MR. SNELL:</p> <p>16 Q. And I think we've seen or you produced</p> <p>17 earlier, as I recall, slide decks, maybe more than one.</p> <p>18 Do you recollect during your professional education</p> <p>19 activities talking to pelvic floor surgeons about the</p> <p>20 potential risk and how to utilize and insert these</p> <p>21 devices?</p> <p>22 MR. SCHNIEDERS: Object to the form.</p> <p>23 THE WITNESS: Yes. We specifically</p> <p>24 would go over techniques, strategies to</p>

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<p>1 minimize, strategies to recognize the</p> <p>2 potential.</p> <p>3 BY MR. SNELL:</p> <p>4 Q. You were asked about the TVT Secur</p> <p>5 randomized control trial.</p> <p>6 Do you recollect that?</p> <p>7 A. I was asked about the security trial,</p> <p>8 which compared TVT retropubic with TVT Secur.</p> <p>9 Q. Was your site paid by Ethicon? I just</p> <p>10 want to understand, because I think there was</p> <p>11 questioning about that, and I got a little unclear.</p> <p>12 A. I understand.</p> <p>13 MR. SCHNIEDERS: Object to the form.</p> <p>14 THE WITNESS: My recollection is that we</p> <p>15 were paid by the Cleveland Clinic. I might</p> <p>16 have earlier mentioned that the money came from</p> <p>17 the foundation, but I do believe that the</p> <p>18 actual payments came through the Cleveland</p> <p>19 Clinic Foundation.</p> <p>20 BY MR. SNELL:</p> <p>21 Q. You were asked questions about whether</p> <p>22 you were an expert in pathology. Let me ask you this:</p> <p>23 In your review of the medical literature, have you</p> <p>24 reviewed the pathology papers with the</p>	<p>1 CERTIFICATION</p> <p>2 I, MARGARET M. REIHL, a Registered</p> <p>3 Professional Reporter, Certified Realtime</p> <p>4 Reporter, Certified Shorthand Reporter,</p> <p>5 Certified LiveNote Reporter and Notary Public,</p> <p>6 do hereby certify that the foregoing is a true</p> <p>7 and accurate transcript of the testimony as</p> <p>8 taken stenographically by and before me at the</p> <p>9 time, place, and on the date hereinbefore set</p> <p>10 forth.</p> <p>11 I DO FURTHER CERTIFY that I am</p> <p>12 neither a relative nor employee nor attorney</p> <p>13 nor counsel of any of the parties to this</p> <p>14 action, and that I am neither a relative nor</p> <p>15 employee of such attorney or counsel, and that</p> <p>16 I am not financially interested in the action.</p> <p>17</p> <p>18</p> <p>19 -----</p> <p>20 Margaret M. Reihl, RPR, CRR, CLR</p> <p>21 CSR #XI01497 Notary Public</p> <p>22</p> <p>23</p> <p>24</p>
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<p>1 photomicrographs, such as the Clave study?</p> <p>2 MR. SCHNIEDERS: Object to the form.</p> <p>3 THE WITNESS: Yes, I've reviewed the</p> <p>4 studies as we've listed them involving the</p> <p>5 scanning electron microscopy using the Fournier</p> <p>6 method of analysis, the optical method of</p> <p>7 analysis as well, the histologic -- several</p> <p>8 histologic studies.</p> <p>9 BY MR. SNELL:</p> <p>10 Q. And based upon your medical education</p> <p>11 and training, were you able to adequately evaluate</p> <p>12 those pathologic studies?</p> <p>13 MR. SCHNIEDERS: Object to the form.</p> <p>14 THE WITNESS: Yes, I think I have an</p> <p>15 excellent working knowledge of those topics.</p> <p>16 MR. SNELL: That's all I have. Thank</p> <p>17 you for your time.</p> <p>18 (Witness excused.)</p> <p>19 (Deposition concluded at 7:17 p.m.)</p> <p>20 ---</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 - - - - -</p> <p>2 E R R A T A</p> <p>3 - - - - -</p> <p>4 PAGE LINE CHANGE</p> <p>5 _____</p> <p>6 REASON: _____</p> <p>7 _____</p> <p>8 REASON: _____</p> <p>9 _____</p> <p>10 REASON: _____</p> <p>11 _____</p> <p>12 REASON: _____</p> <p>13 _____</p> <p>14 REASON: _____</p> <p>15 _____</p> <p>16 REASON: _____</p> <p>17 _____</p> <p>18 REASON: _____</p> <p>19 _____</p> <p>20 REASON: _____</p> <p>21 _____</p> <p>22 REASON: _____</p> <p>23 _____</p> <p>24 REASON: _____</p>

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Marc R. Toggia, M.D.

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ACKNOWLEDGMENT OF DEPONENT

I, MARC R. TOGLIA, M.D., do hereby
 certify that I have read the foregoing pages,
 and that the same is a correct transcription of
 the answers given by me to the questions
 therein propounded, except for the corrections
 or changes in form or substance, if any, noted
 in the attached Errata Sheet.

 MARC R. TOGLIA, M.D. DATE

Subscribed and sworn to before me this

_____ day of _____, 2016.

My commission expires: _____

 Notary Public